Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

ISRCTN Results System Prototype (link)

Summary of the PHUSE Data Transparency Working Group's Feedback Submitted Online Via Prototype Link

Form fields highlighted in purple

Role, organisation or other information:

Dear ISRCTN Team

We would like to thank you for the opportunity to review and provide feedback on the new results system prototype. The feedback was developed by a diverse group of experts from the PHUSE Data Transparency Working Group.

For the purposes of providing feedback, we have tested the fields, and we are not submitting any results. We noticed the option to submit the form is greyed out since the ISRCTN results system prototype disables the submit button while in Review Mode. I am pleased to share a summary of comments, included in the ISRCTN results system prototype feedback collated from our review at PHUSE.

We are an independent, not-for-profit organisation run by a worldwide team of volunteers providing the healthcare industry with a premier platform for open-access knowledge sharing of ideas, tools and standards around data, statistical and reporting technologies. PHUSE has become the industry voice to regulatory agencies and standards organisations such as the FDA, the EMA and CDISC.

Our team have very much enjoyed being part of this important initiative to give feedback and drive forward the future of clinical trials.

Please feel free to reach out if you have any queries.

Many thanks

Devaki Thavarajah
PHUSE Data Transparency Working Group Lead
devaki.thavarajah@phuse.global

Respectfully submitted on behalf of the PHUSE Data Transparency Working Group

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

Please tell us about your experience with registries:

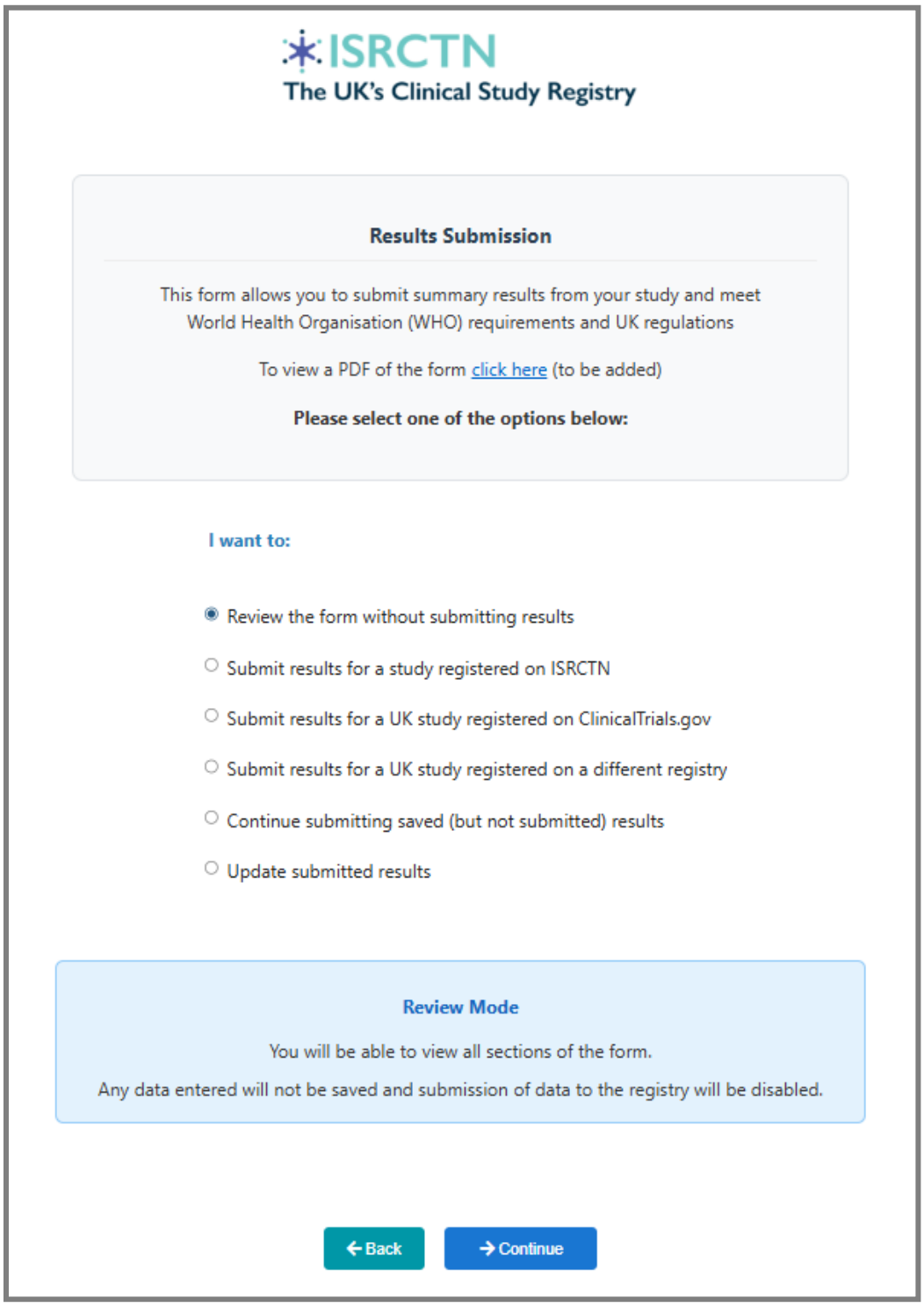
- ○ I register most studies on ISRCTN
- ◉ I register most studies on ClinicalTrials.gov/another registry
- ○ I do not register studies

Please provide any additional information such as your role and organisation

Enter your role, organisation or other information...

→ Click here to review the form

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ



E-mail office@phuse.global
Web www.phuse.global

PHUSE Limited
Company No: 05422297
VAT No: GB920 0529 64

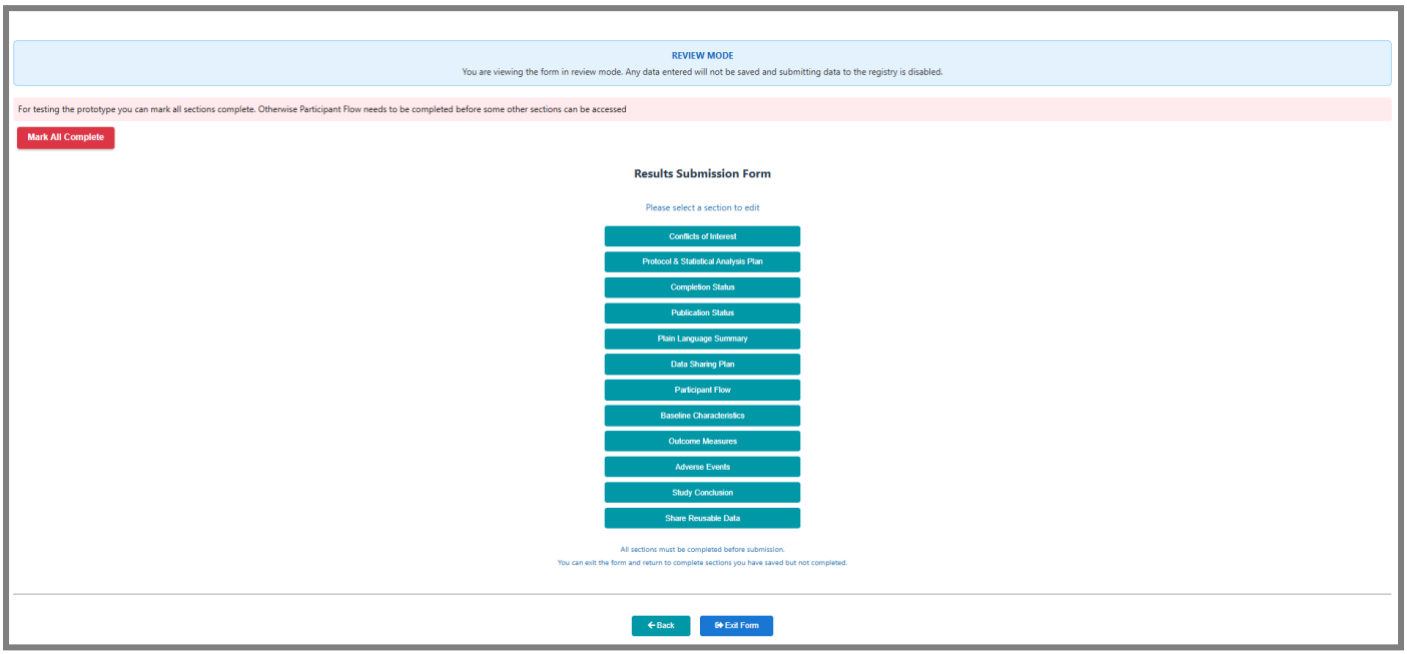
PHUSE CTR
(wholly owned European subsidiary of PHUSE Limited)
Company No: 750562

PHUSE India Private Limited
Corporate Identity No: U82300PN2024FTC236151
GST No: 27AAPCP2555B1ZE
PAN No: AAPCP2555B

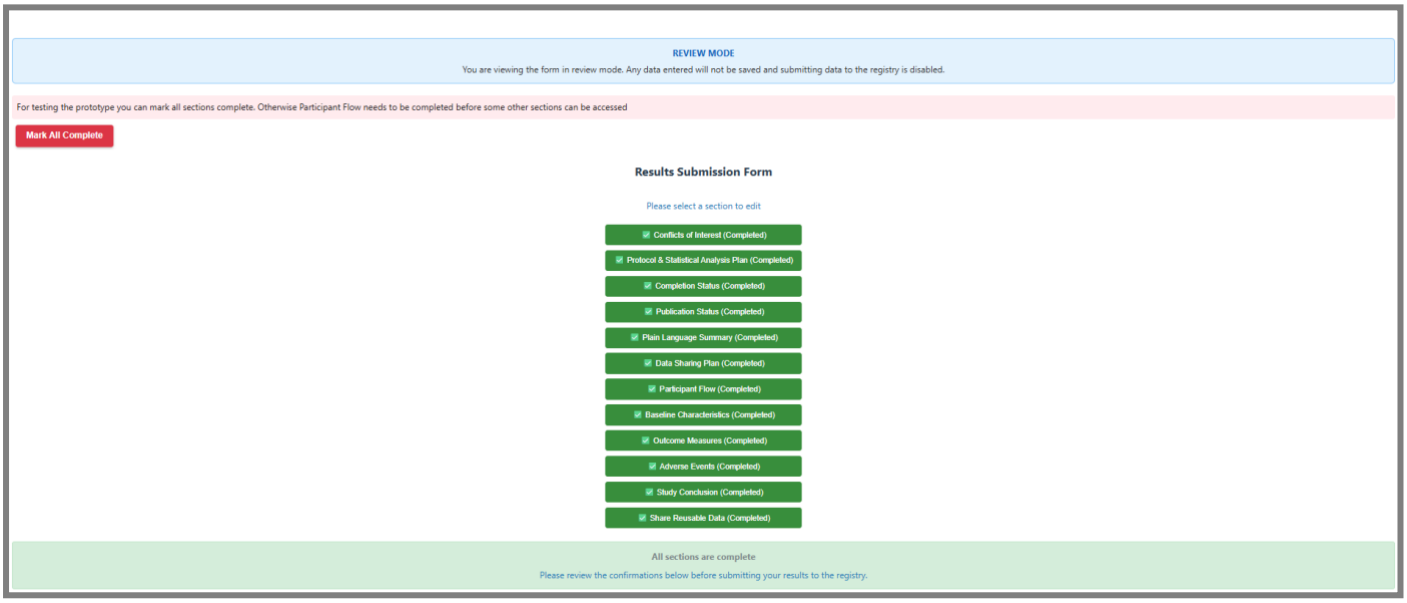
Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

Example screenshots:

Results Sections Contents Page – Before Completion



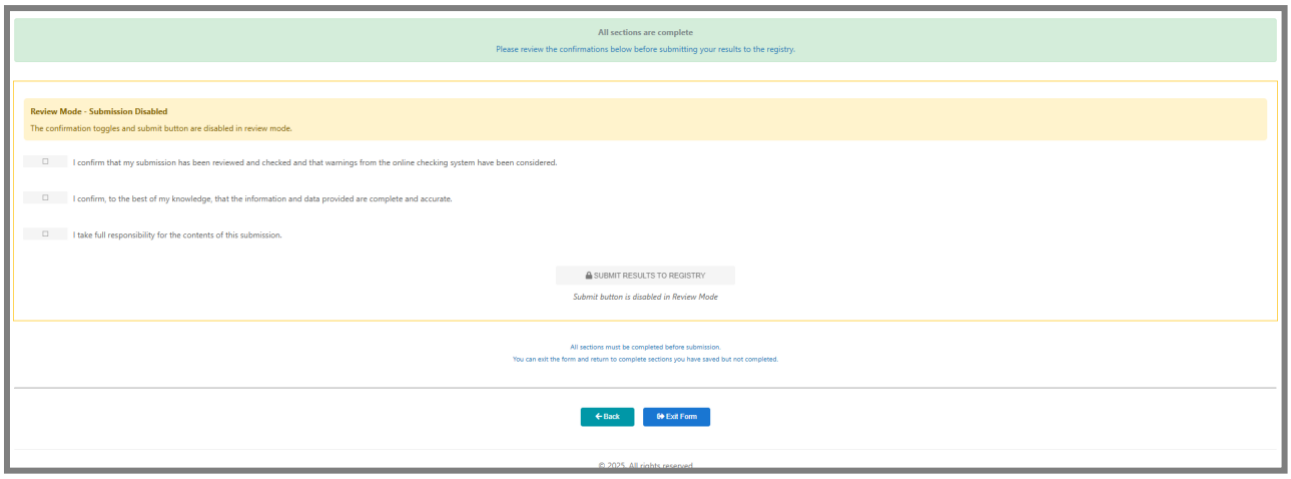
Results Sections Contents Page – After Completion



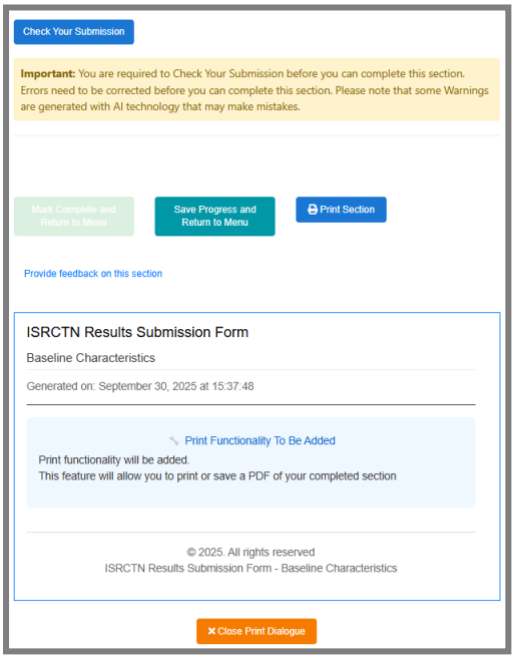
Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

Page disclaimer located at the bottom of the Contents page:

(Checkboxes are greyed out since the ISRCTN results system prototype disables the submit button in Review Mode.)



FORM SECTIONS



E-mail office@phuse.global

Web www.phuse.global

PHUSE Limited
Company No: 05422297
VAT No: GB920 0529 64

PHUSE CTR
(wholly owned European subsidiary of PHUSE Limited)
Company No: 750562

PHUSE India Private Limited
Corporate Identity No: U82300PN2024FTC236151
GST No: 27AAPCP2555B1ZE
PAN No: AAPCP2555B

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

Potential Conflicts of Interest:

WHO requirement: Conflicts of interest for study steering group members are included in the registry summary results.

Please help us improve this form by providing feedback on this section:

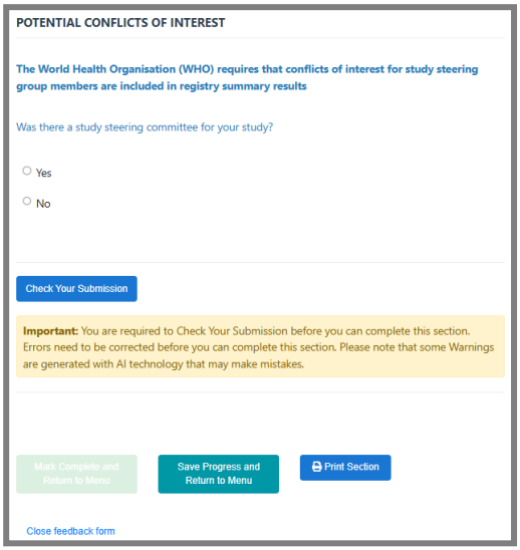
1. How easy will it be to complete this section?

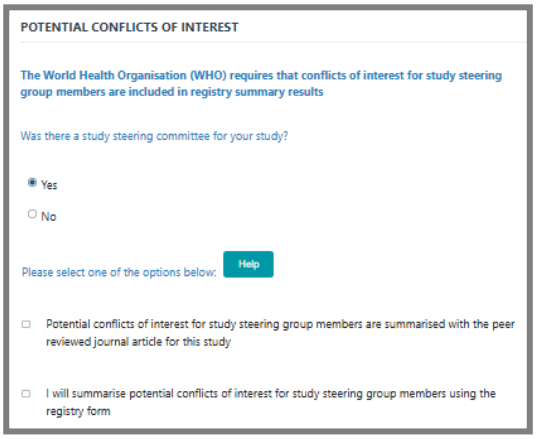
Very easy | **Moderately easy** | **Not easy**

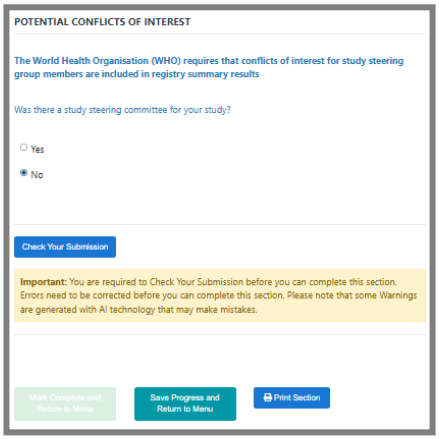
PHUSE Response Selection:
Not easy

2. What suggestions would you make to improve this section?

- Suggest defining conflicts of interest. (There is no definition on the web form or any links to where this information can be found.) Also define who is considered a steering committee member.







Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

Protocol & Statistical Analysis Plan:

WHO requirement: The final study protocol (with version number, date and history of amendments) is included in the registry summary results.

Please help us improve this form by providing feedback on this section:

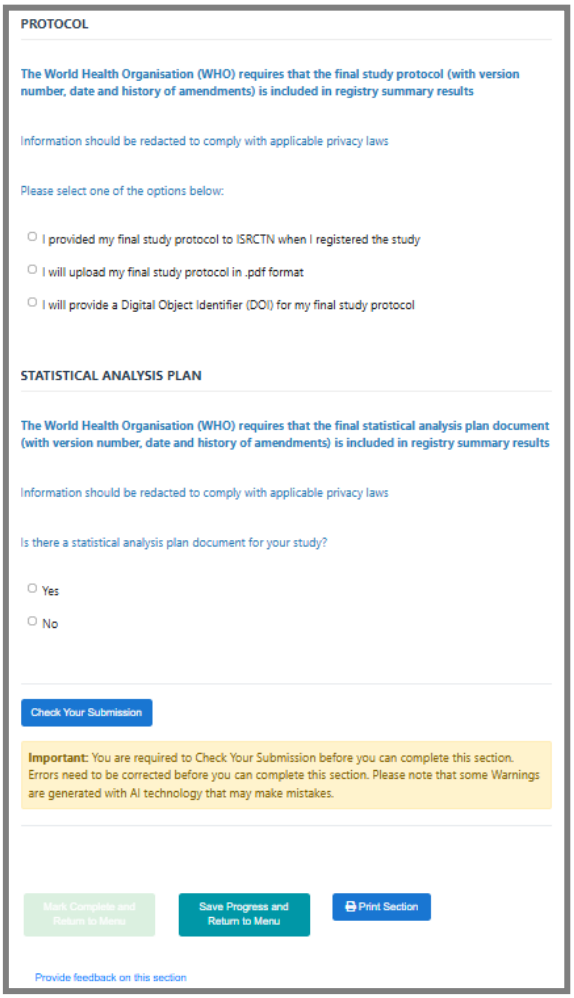
1. How easy will it be to complete this section?

Very easy | **Moderately easy** | **Not easy**

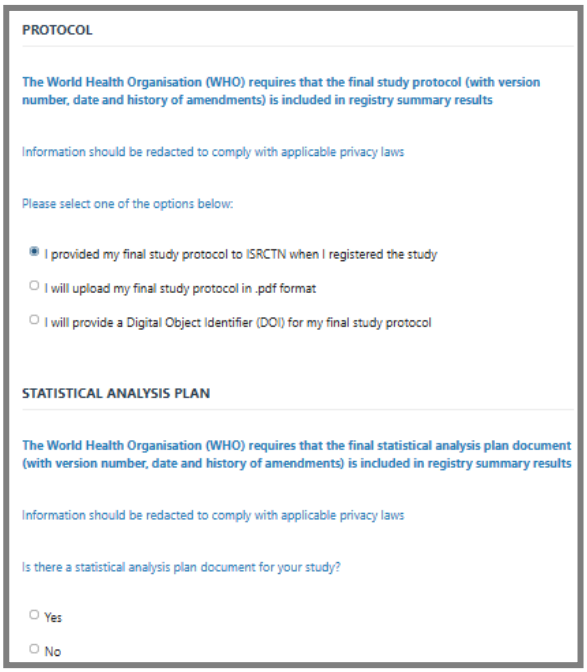
PHUSE Response Selection:
Moderately easy

2. What suggestions would you make to improve this section?

No comments



Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ



PROTOCOL

The World Health Organisation (WHO) requires that the final study protocol (with version number, date and history of amendments) is included in registry summary results

Information should be redacted to comply with applicable privacy laws

Please select one of the options below:

- (●) I provided my final study protocol to ISRCTN when I registered the study
- ( ) I will upload my final study protocol in .pdf format
- ( ) I will provide a Digital Object Identifier (DOI) for my final study protocol

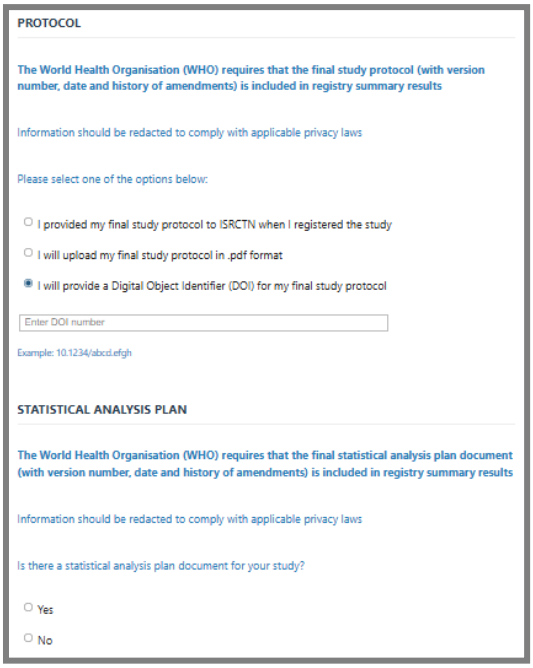
STATISTICAL ANALYSIS PLAN

The World Health Organisation (WHO) requires that the final statistical analysis plan document (with version number, date and history of amendments) is included in registry summary results

Information should be redacted to comply with applicable privacy laws

Is there a statistical analysis plan document for your study?

- ( ) Yes
- ( ) No



PROTOCOL

The World Health Organisation (WHO) requires that the final study protocol (with version number, date and history of amendments) is included in registry summary results

Information should be redacted to comply with applicable privacy laws

Please select one of the options below:

- ( ) I provided my final study protocol to ISRCTN when I registered the study
- ( ) I will upload my final study protocol in .pdf format
- (●) I will provide a Digital Object Identifier (DOI) for my final study protocol

Enter DOI number

Example: 10.1234/abcd.efgh

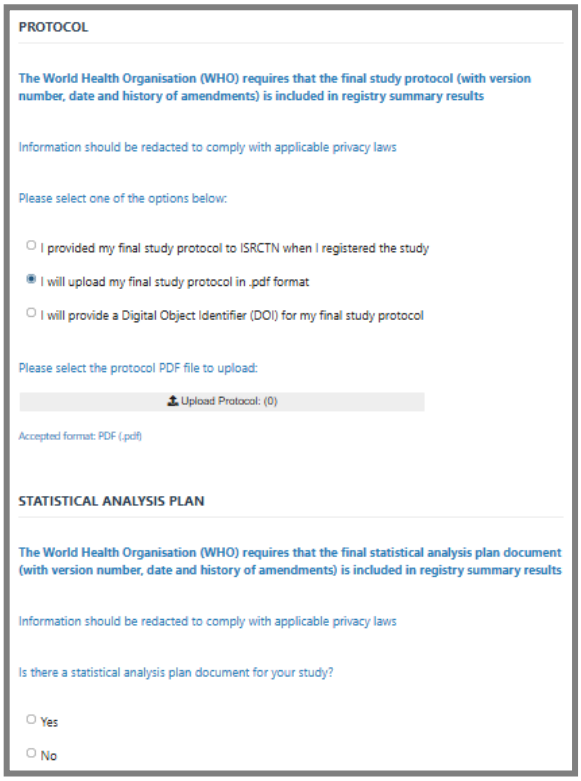
STATISTICAL ANALYSIS PLAN

The World Health Organisation (WHO) requires that the final statistical analysis plan document (with version number, date and history of amendments) is included in registry summary results

Information should be redacted to comply with applicable privacy laws

Is there a statistical analysis plan document for your study?

- ( ) Yes
- ( ) No



PROTOCOL

The World Health Organisation (WHO) requires that the final study protocol (with version number, date and history of amendments) is included in registry summary results

Information should be redacted to comply with applicable privacy laws

Please select one of the options below:

- ( ) I provided my final study protocol to ISRCTN when I registered the study
- (●) I will upload my final study protocol in .pdf format
- ( ) I will provide a Digital Object Identifier (DOI) for my final study protocol

Please select the protocol PDF file to upload:

Upload Protocol: (0)

Accepted format: PDF (.pdf)

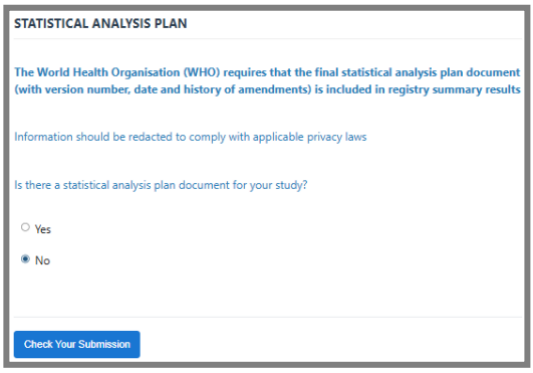
STATISTICAL ANALYSIS PLAN

The World Health Organisation (WHO) requires that the final statistical analysis plan document (with version number, date and history of amendments) is included in registry summary results

Information should be redacted to comply with applicable privacy laws

Is there a statistical analysis plan document for your study?

- ( ) Yes
- ( ) No



STATISTICAL ANALYSIS PLAN

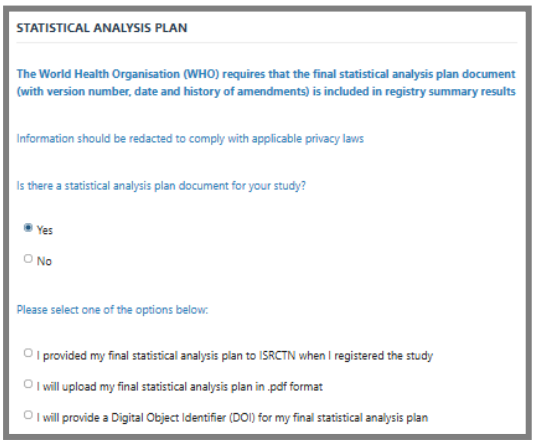
The World Health Organisation (WHO) requires that the final statistical analysis plan document (with version number, date and history of amendments) is included in registry summary results

Information should be redacted to comply with applicable privacy laws

Is there a statistical analysis plan document for your study?

- ( ) Yes
- (●) No

Check Your Submission



STATISTICAL ANALYSIS PLAN

The World Health Organisation (WHO) requires that the final statistical analysis plan document (with version number, date and history of amendments) is included in registry summary results

Information should be redacted to comply with applicable privacy laws

Is there a statistical analysis plan document for your study?

- (●) Yes
- ( ) No

Please select one of the options below:

- ( ) I provided my final statistical analysis plan to ISRCTN when I registered the study
- ( ) I will upload my final statistical analysis plan in .pdf format
- ( ) I will provide a Digital Object Identifier (DOI) for my final statistical analysis plan

E-mail office@phuse.global

Web www.phuse.global

PHUSE Limited
Company No: 05422297
VAT No: GB920 0529 64

PHUSE CTR
(wholly owned European subsidiary of PHUSE Limited)
Company No: 750562

PHUSE India Private Limited
Corporate Identity No: U82300PN2024FTC236151
GST No: 27AAPCP2555B1ZE
PAN No: AAPCP2555B

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

Completion Status:

WHO requirement: The completion status and completion date for your study are included in the registry summary results.

Please help us improve this form by providing feedback on this section:

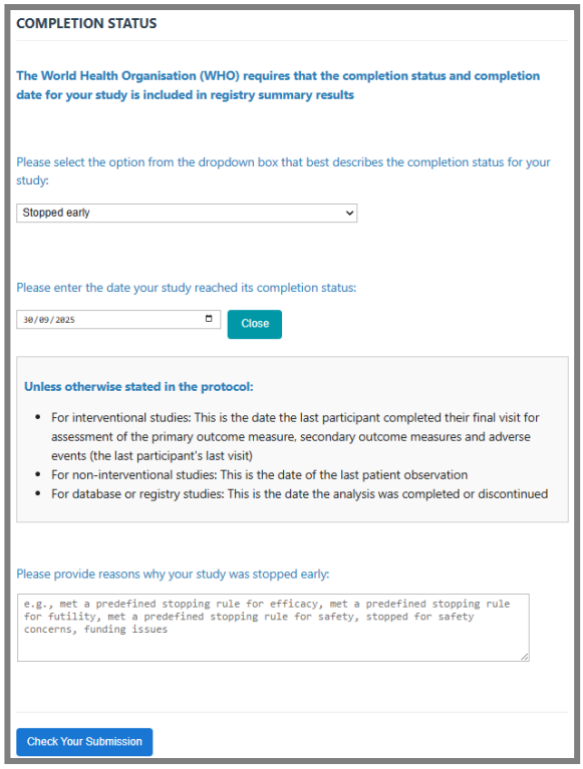
1. How easy will it be to complete this section?

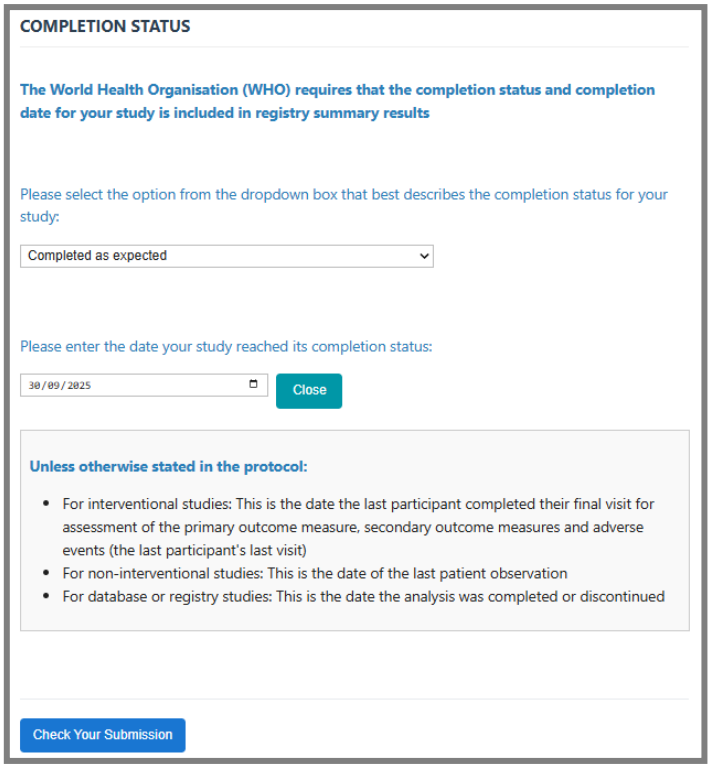
Very easy | **Moderately easy** | **Not easy**

PHUSE Response Selection:
Moderately easy

2. What suggestions would you make to improve this section?

No comments





E-mail office@phuse.global

Web www.phuse.global

PHUSE Limited
Company No: 05422297
VAT No: GB920 0529 64

PHUSE CTR
(wholly owned European subsidiary of PHUSE Limited)
Company No: 750562

PHUSE India Private Limited
Corporate Identity No: U82300PN2024FTC236151
GST No: 27AAPCP2555B1ZE
PAN No: AAPCP2555B

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

Publication Status:

WHO requirement: The date and digital object identifier for the journal publication of the primary results are included in the registry summary results.

Please help us improve this form by providing feedback on this section:

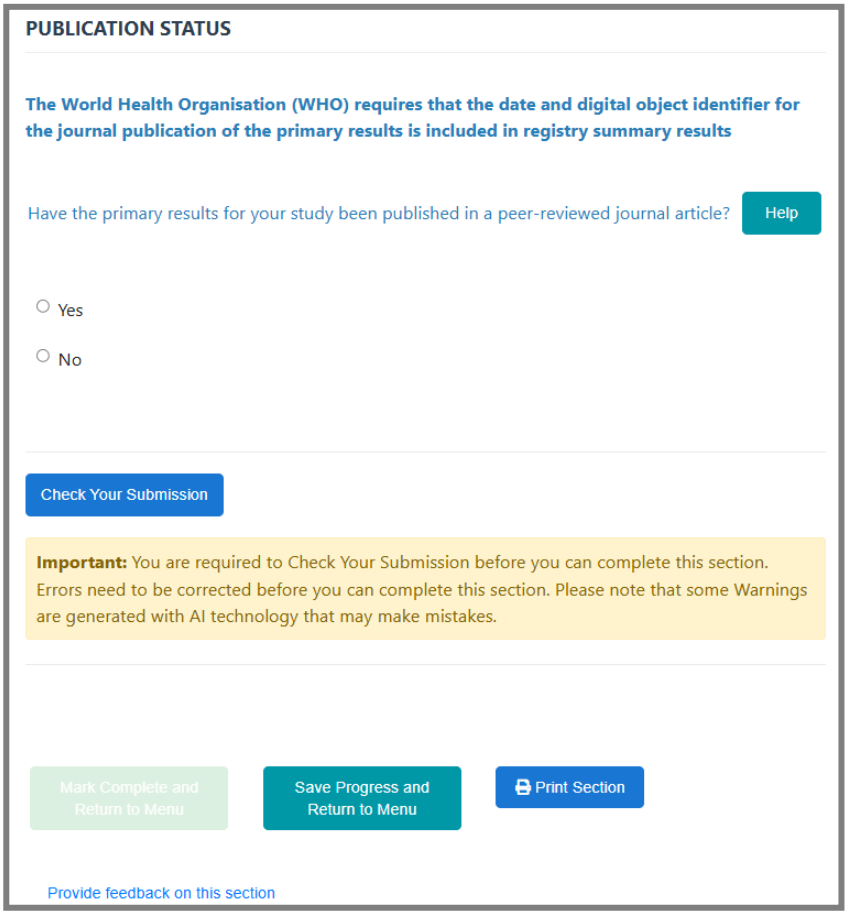
1. How easy will it be to complete this section?

Very easy | **Moderately easy** | **Not easy**

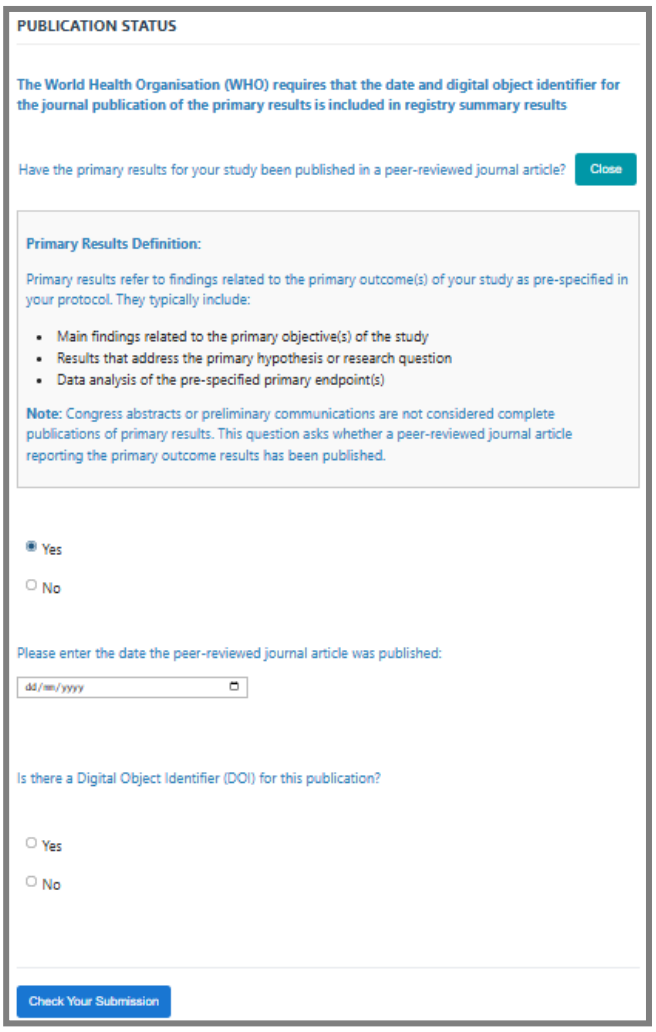
PHUSE Response Selection:
Moderately easy

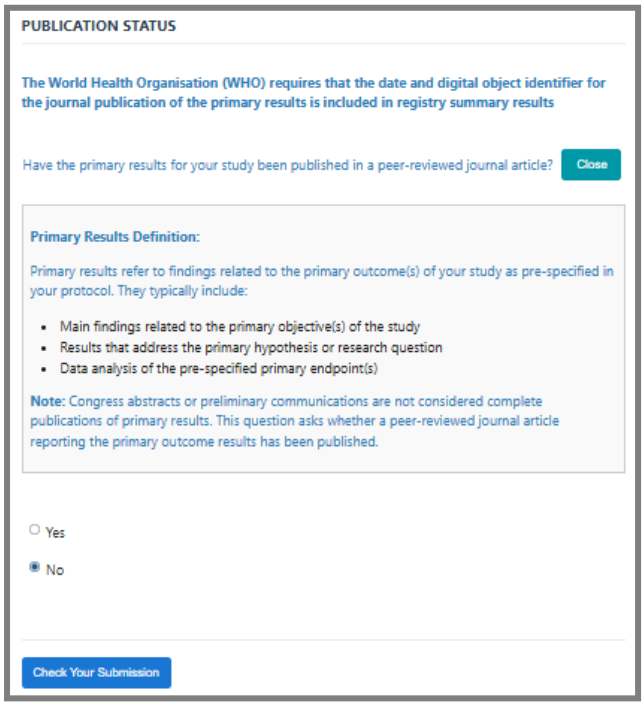
2. What suggestions would you make to improve this section?

No comments



Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ





E-mail office@phuse.global

Web www.phuse.global

PHUSE Limited
Company No: 05422297
VAT No: GB920 0529 64

PHUSE CTR
(wholly owned European subsidiary of PHUSE Limited)
Company No: 750562

PHUSE India Private Limited
Corporate Identity No: U82300PN2024FTC236151
GST No: 27AAPCP2555B1ZE
PAN No: AAPCP2555B

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

Plain Language Summary of Results:

The WHO does not require plain language summaries (PLSs) of results to be included in the registry summary results.

Please help us improve this form by providing feedback on this section:

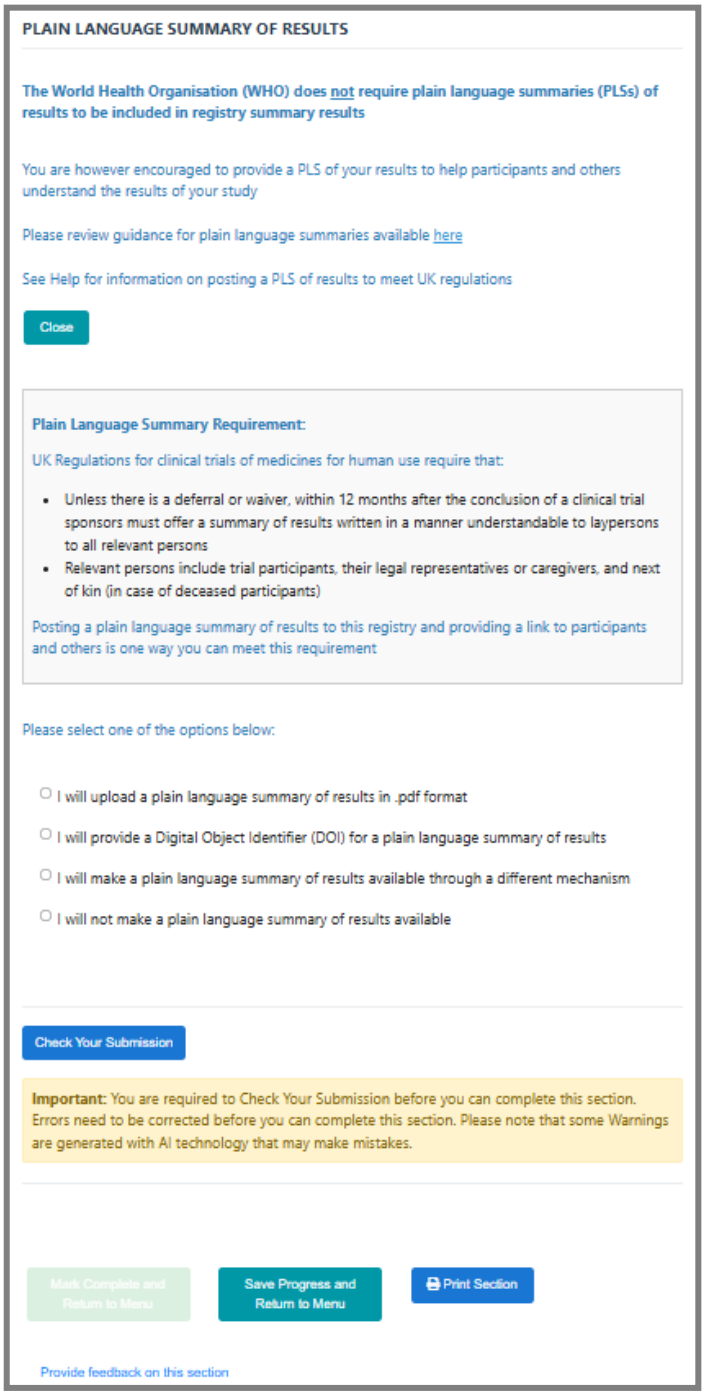
1. How easy will it be to complete this section?

Very easy | **Moderately easy** | **Not easy**

PHUSE Response Selection:
Moderately easy

2. What suggestions would you make to improve this section?

No comments



Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

Data Sharing Plan:
WHO requirement: The data sharing plans are updated as needed after study completion.

Please help us improve this form by providing feedback on this section:

1. How easy will it be to complete this section?

Very easy | **Moderately easy** | **Not easy**

PHUSE Response Selection:
Moderately easy

2. What suggestions would you make to improve this section?

- General comment: It would be helpful to mark on the form the fields from IRAS which are posted in the public domain.

- In some organisations, another department populates the IRAS form, so perhaps it would be helpful to have an option for the person completing the form to include additional member contact details; to allow the form submission to be viewed by the other interested groups; and to show which fields were selected to opt in for auto-registration so the interested groups can also prepare for the next steps and maintain compliance.

- Formatting: In instances where there is a prompt to select one option ("Please select one of the options below:"), square checkboxes are used. Typically, square boxes are used when there are multiple options to select. Therefore, we suggest changing square boxes to circular because circles are usually used when there is only one option to select.

  Note: This comment applies to all instances throughout the form when square boxes are used and the user is required to select only one option.

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

DATA SHARING

The World Health Organisation (WHO) requires that data sharing plans are updated as needed after study completion

This is the data sharing plan you provided when you registered this study:

[Data sharing plan from ISRCTN or ClinicalTrials.gov displayed here].

Please select one of the options below:

- ☐ The data sharing plan for my study has not changed
- ☐ I will update the data sharing plan for my study
  (also select this option if your study is not registered on ISRCTN or ClinicalTrials.gov)

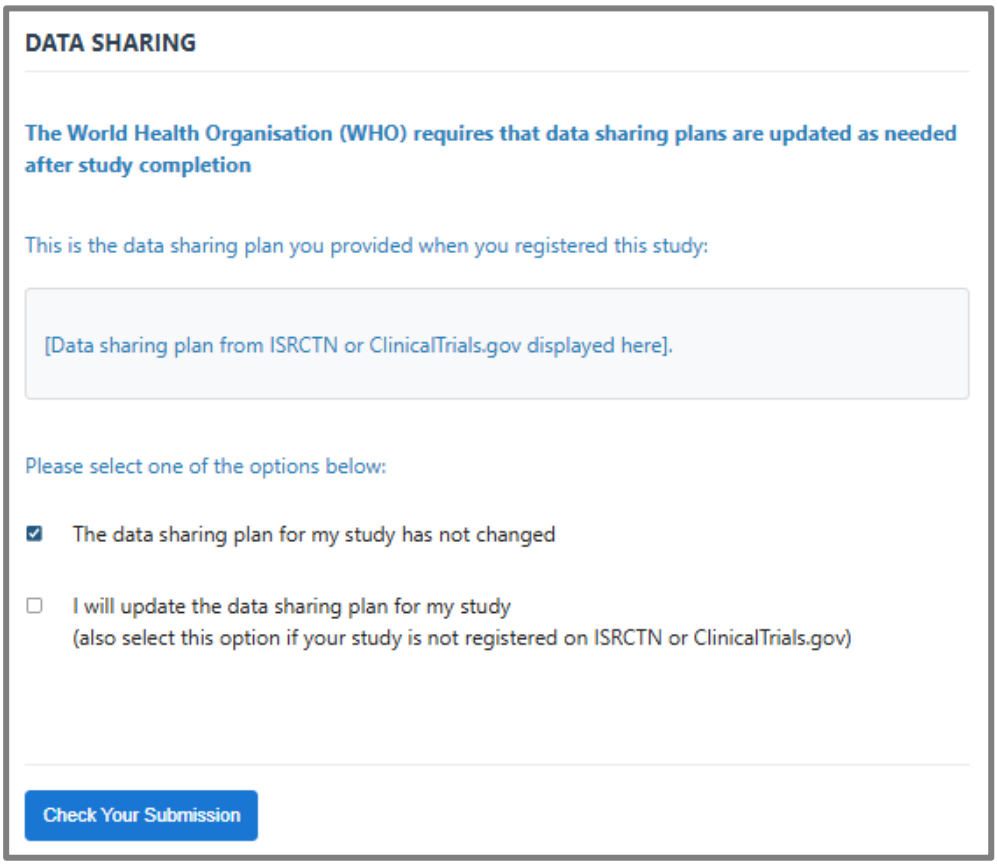
Check Your Submission

Important: You are required to Check Your Submission before you can complete this section. Errors need to be corrected before you can complete this section. Please note that some Warnings are generated with AI technology that may make mistakes.

Mark Complete and Return to Menu | Save Progress and Return to Menu | Print Section

Provide feedback on this section

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ



E-mail office@phuse.global

Web www.phuse.global

PHUSE Limited
Company No: 05422297
VAT No: GB920 0529 64

PHUSE CTR
(wholly owned European subsidiary of PHUSE Limited)
Company No: 750562

PHUSE India Private Limited
Corporate Identity No: U82300PN2024FTC236151
GST No: 27AAPCP2555B1ZE
PAN No: AAPCP2555B

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

DATA SHARING

The World Health Organisation (WHO) requires that data sharing plans are updated as needed after study completion

This is the data sharing plan you provided when you registered this study:

[Data sharing plan from ISRCTN or ClinicalTrials.gov displayed here].

Please select one of the options below:

- [ ] The data sharing plan for my study has not changed
- [x] I will update the data sharing plan for my study
  (also select this option if your study is not registered on ISRCTN or ClinicalTrials.gov)

Update or provide your data sharing plan:

[Data sharing plan from ISRCTN or ClinicalTrials.gov displayed here].

Check Your Submission

E-mail office@phuse.global

Web www.phuse.global

PHUSE Limited
Company No: 05422297
VAT No: GB920 0529 64

PHUSE CTR
(wholly owned European subsidiary of PHUSE Limited)
Company No: 750562

PHUSE India Private Limited
Corporate Identity No: U82300PN2024FTC236151
GST No: 27AAPCP2555B1ZE
PAN No: AAPCP2555B

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

Participant Flow:

WHO requirement: Information relating to the flow of participants through the study, from enrolment to inclusion in the main analysis of the primary outcome measure, is included in the registry summary results.

Please help us improve this form by providing feedback on this section:

1. How easy will it be to complete this section?

Very easy | **Moderately easy** | **Not easy**

PHUSE Response Selection:
Not easy

2. What suggestions would you make to improve this section?

- General comment regarding the 'Mark All Complete' button in the top left corner of the main menu: Suggestion for the system to include additional verification and pointers for the required amendments (within each section and on the contents/main menu page) because this button may be selected without the record being completed correctly.

- This section is complex and must be completed before being able to continue to the remaining sections. The system includes validation checks but could be improved for user-friendliness.

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

PARTICIPANT FLOW

The World Health Organisation (WHO) requires that information relating to the flow of participants through the study from enrollment to inclusion in the main analysis of the primary outcome measure is included in registry summary results

You have the option to also provide participant flow information for other parts, cohorts or periods of your study where this would help others understand your study

Information on participant flow is based on the CONSORT approach Help

Please select one of the options below:

- [x] I will provide participant flow information for WHO requirements only - the number allocated to study arms/groups and included in the main analysis of the primary outcome measure

- [ ] I will provide participant flow information for WHO requirements **and for other parts, cohorts or periods in my study**

Total Number of Participants

Please enter the total number of participants enrolled in your study before allocation to study arms/groups:

Total Participants: 0

Note: This should be the total number of participants who were enrolled before randomisation or allocation to study arms/groups (e.g., number assessed for eligibility).

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

PARTICIPANT FLOW

The World Health Organisation (WHO) requires that information relating to the flow of participants through the study from enrollment to inclusion in the main analysis of the primary outcome measure is included in registry summary results

You have the option to also provide participant flow information for other parts, cohorts or periods of your study where this would help others understand your study

Information on participant flow is based on the CONSORT approach Close

CONSORT 2025 Flow Diagram

The diagram below shows participant progress through the phases of a two group, parallel randomised trial:

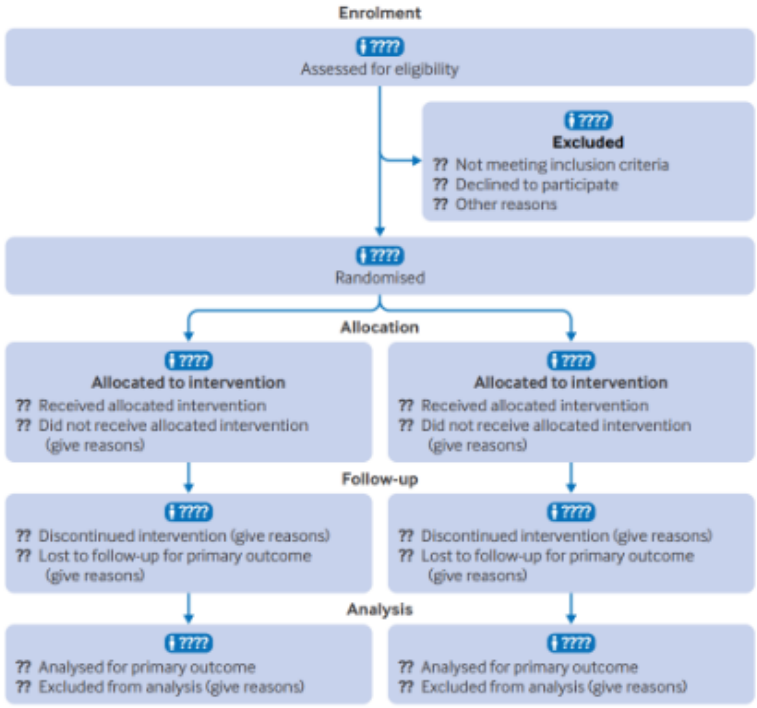


Fig 1 | CONSORT 2025 flow diagram. Flow diagram of participant progress through the phases of a two group, parallel randomised trial (ie, enrolment, intervention allocation, follow-up, and data analysis). CONSORT=Consolidated Standards of Reporting Trials

Close

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

Study Arms/Groups

Please enter the number of study arms/groups in your study: Help

2

Please enter a description for each arm/group:

Arm/Group 1: e.g., Placebo

Arm/Group 2: e.g., Treatment A

Note: The number of Arms/Groups and descriptions are applied to all relevant registry tables. If you change the number of Arms/Groups or their descriptions these changes will be applied throughout the form.

Participant Flow Information

Please select how you would like to provide participant flow information:

☑ I will upload participant flow information table(s) and/or figure(s) in .pdf format

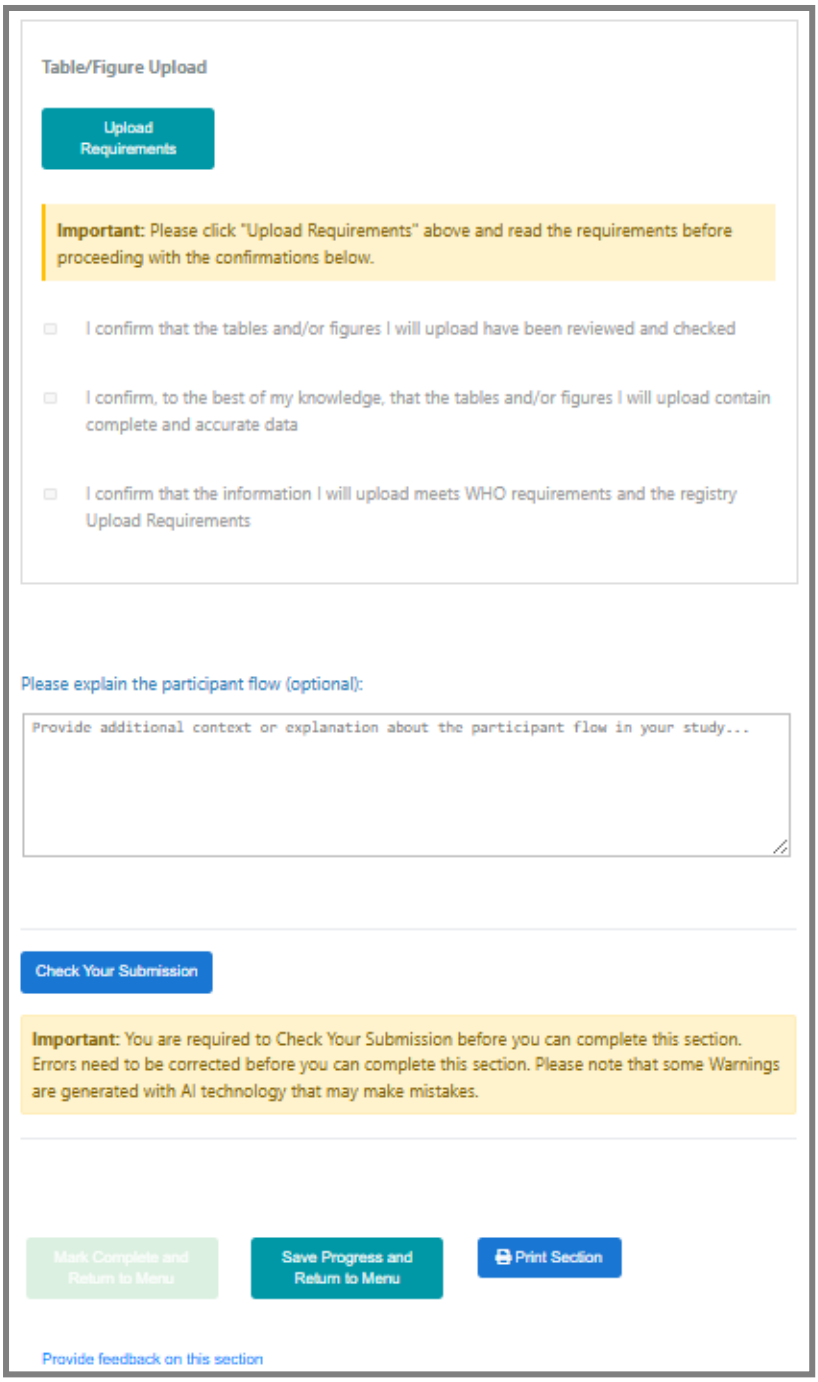
> ℹ Select this option if it is difficult to use the registry tables to describe participant flow for your study or if it is easier to provide accurate and complete data.

☐ I will provide participant flow information by completing registry tables

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

Options:

PDF UPLOAD



Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

REGISTRY RESULTS TABLE UPLOAD

Participant Flow Information

Please select how you would like to provide participant flow information:

☐ I will upload participant flow information table(s) and/or figure(s) in .pdf format

> ℹ Select this option if it is difficult to use the registry tables to describe participant flow for your study or if it is easier to provide accurate and complete data.

☑ I will provide participant flow information by completing registry tables

Create/Update Table with Descriptions

Number of Participants

Please complete the table below by entering the number of participants:

Number of Participants	Arm/Group 1	Arm/Group 2	Study Population
Allocated to Study Treatment(s)	0	0	0
Included in the Main Analysis of the Primary Outcome Measure(s)	0	0	0
Included in Study Part, Cohort or Period 1	0	0	0

E-mail office@phuse.global

Web www.phuse.global

PHUSE Limited
Company No: 05422297
VAT No: GB920 0529 64

PHUSE CTR
(wholly owned European subsidiary of PHUSE Limited)
Company No: 750562

PHUSE India Private Limited
Corporate Identity No: U82300PN2024FTC236151
GST No: 27AAPCP2555B1ZE
PAN No: AAPCP2555B

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

Reasons for Non-completion for Each Arm/Group

For each arm/group, provide the reasons for exclusion
(Note: There is one table for each arm/group)

Close

Help:

- Enter the number of participants who were excluded for the reasons specified in the table. If a participant was excluded for more than one reason count only one reason (the main reason). Do not count the same participant in more than one row. If no partcipants were excluded for a specified reason leave the number as "0". Delete rows with all zeros using the button at the bottom of each table.
- For participants who **Did not Receive Any Study Treatment as Allocated** include only participants who were allocated to a study treatment group but did not receive any part of the assigned treatment (e.g., did not start treatment). Do not include participants who received part but not all of the assigned treatment.
- **Lost to Follow-up** specifically refers to participants who were enrolled and assigned to a treatment group but did not complete the study or a study period because they could not be contacted or failed to return for follow-up assessments. This is distinct from other reasons for non-completion, such as adverse events or participant withdrawal.
- If there are other specific reasons that are not included in the table, use the box below the table to add specific reasons to the table. Reasons added in error can be deleted.
- Use the **Other Reason Excluded from Analysis** row for participants excluded from the analysis for reasons not captured elsewhere in the table. For example, if the analysis was conducted in a per-protocol population, include here any participants excluded due to not meeting those criteria (e.g., missing key visits, non-adherence), provided a more specific reason (e.g., protocol violation, withdrawal) does not apply.
- For **interim analyses** add a reason "not recruited at the time of the interim analysis".

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

Arm/Group 1 - Reasons	Did not Receive Any Study Treatment as Allocated	Excluded from the Main Analysis of the Primary Outcome Measure(s)	Excluded fro Study Part, Col or Period 1
Adverse Event	0	0	0
Death	0	0	0
Lack of Efficacy	0	0	0
Protocol Violation	0	0	0
Pregnancy	0	0	0
Participant Withdrawal	0	0	0
Withdrawn by Study Investigator	0	0	0
Lost to Follow-up	0	0	0
Other Reason Excluded from Analysis	N/A	0	0

Add another specific reason for Arm/Group 1 (optional):

Enter another specific reason

Add Reason

Delete All Zero Rows (functionality to be added)

E-mail office@phuse.global

Web www.phuse.global

PHUSE Limited
Company No: 05422297
VAT No: GB920 0529 64

PHUSE CTR
(wholly owned European subsidiary of PHUSE Limited)
Company No: 750562

PHUSE India Private Limited
Corporate Identity No: U82300PN2024FTC236151
GST No: 27AAPCP2555B1ZE
PAN No: AAPCP2555B

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

Arm/Group 2 - Reasons	Did not Receive Any Study Treatment as Allocated	Excluded from the Main Analysis of the Primary Outcome Measure(s)	Excluded f Study Part, C or Period
Adverse Event	0	0	0
Death	0	0	0
Lack of Efficacy	0	0	0
Protocol Violation	0	0	0
Pregnancy	0	0	0
Participant Withdrawal	0	0	0
Withdrawn by Study Investigator	0	0	0
Lost to Follow-up	0	0	0
Other Reason Excluded from Analysis	N/A	0	0

Add another specific reason for Arm/Group 2 (optional):

Enter another specific reason

Add Reason

Delete All Zero Rows (functionality to be added)

Please explain the participant flow (optional):

Provide additional context or explanation about the participant flow in your study...

Check Your Submission

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

Baseline Characteristics:

WHO requirement: Baseline characteristics for age, sex and other relevant characteristics are included in the registry summary results.

Please help us improve this form by providing feedback on this section:

1. How easy will it be to complete this section?

Very easy | **Moderately easy** | **Not easy**

PHUSE Response Selection:
Not easy

2. What suggestions would you make to improve this section?

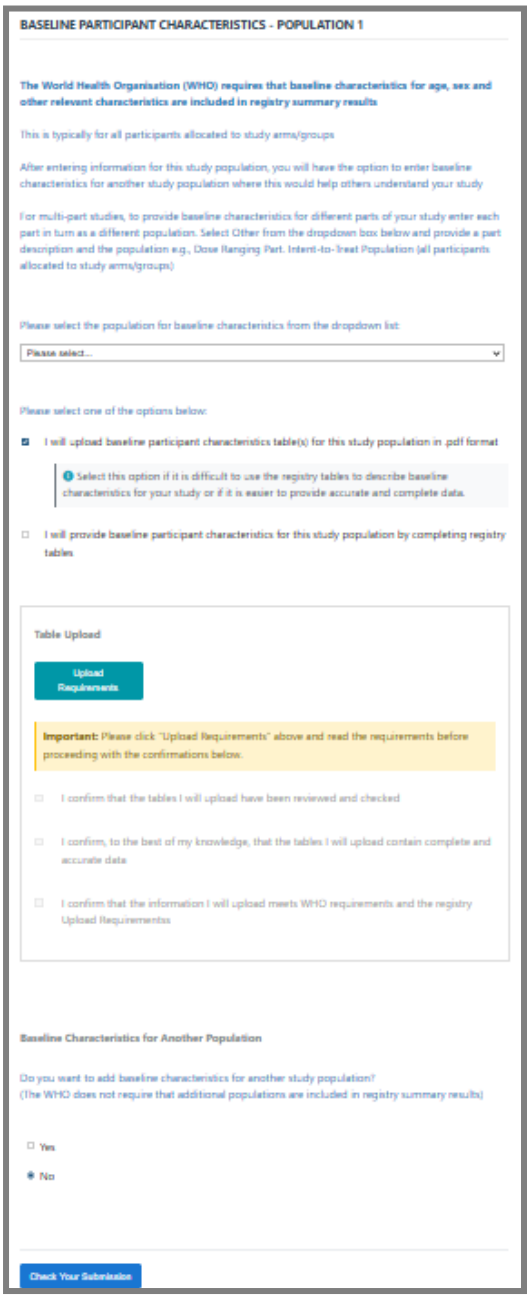
- Users must click on several options to navigate each aspect for completion. An option to reset form fields would be helpful for starting afresh on a particular section or question. Square box options can be unselected, but this is not possible with the circle field options. We suggest simplifying the navigation and data entry user interface experience. The prototype lacks user-friendly features and documentation.

- For sex, the options are: male, female, not recorded as male or female. In some cases – for example, when there is one female in the arm – providing more baseline characteristic information gets you a profile of the patient. There should be an option to show the baseline per overall study so as not to build the profile of a particular patient where the arm is N=1.

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

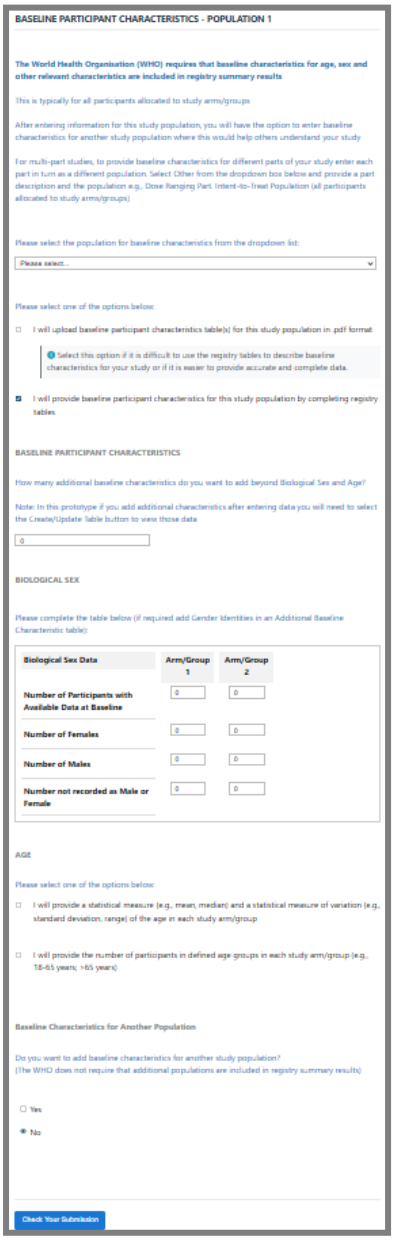
Options:

PDF UPLOAD



Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

REGISTRY RESULTS TABLES UPLOAD



E-mail office@phuse.global

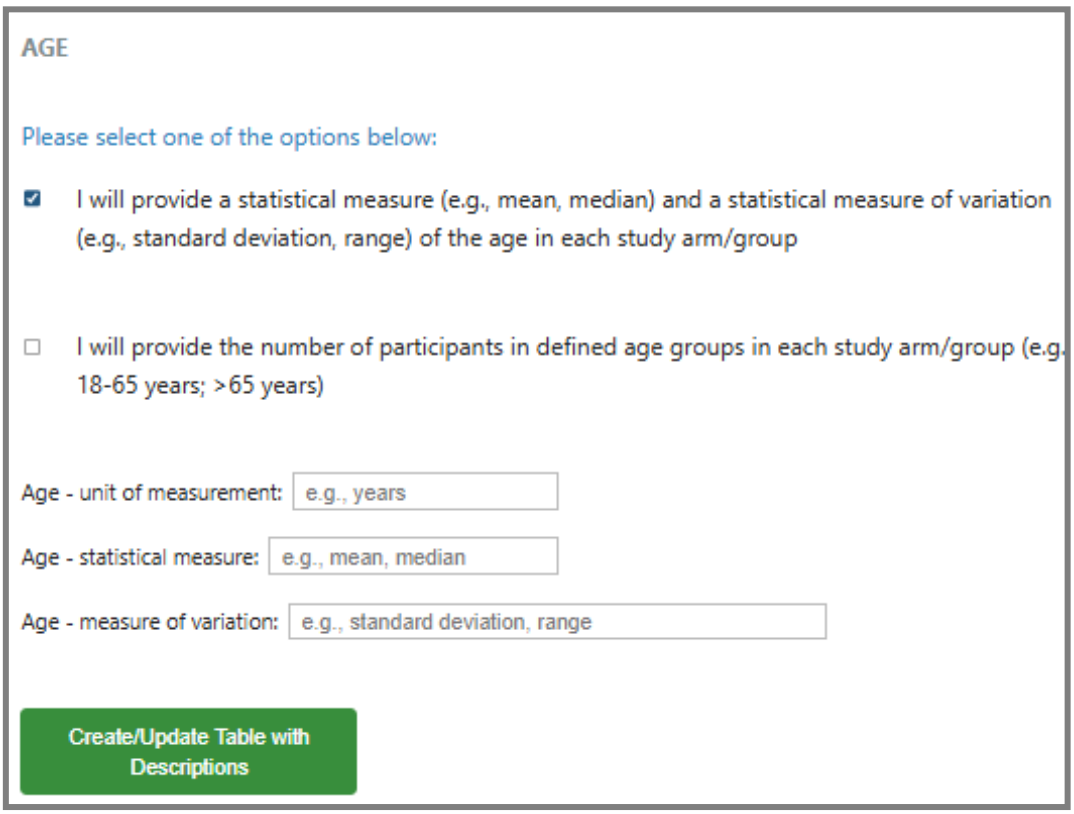
Web www.phuse.global

PHUSE Limited
Company No: 05422297
VAT No: GB920 0529 64

PHUSE CTR
(wholly owned European subsidiary of PHUSE Limited)
Company No: 750562

PHUSE India Private Limited
Corporate Identity No: U82300PN2024FTC236151
GST No: 27AAPCP2555B1ZE
PAN No: AAPCP2555B

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ



E-mail office@phuse.global

Web www.phuse.global

PHUSE Limited
Company No: 05422297
VAT No: GB920 0529 64

PHUSE CTR
(wholly owned European subsidiary of PHUSE Limited)
Company No: 750562

PHUSE India Private Limited
Corporate Identity No: U82300PN2024FTC236151
GST No: 27AAPCP2555B1ZE
PAN No: AAPCP2555B

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

AGE

Please select one of the options below:

- [x] I will provide a statistical measure (e.g., mean, median) and a statistical measure of variation (e.g., standard deviation, range) of the age in each study arm/group
- [ ] I will provide the number of participants in defined age groups in each study arm/group (e.g., 18-65 years; >65 years)

Age - unit of measurement: e.g., years

Age - statistical measure: e.g., mean, median

Age - measure of variation: e.g., standard deviation, range

Create/Update Table with Descriptions

Other Population

Please complete the table below:

Age Data	Arm/Group 1	Arm/Group 2
Number of Participants with Available Data at Baseline	0	0
Unit of Measurement (units)	units	units
Statistical Measure	0	0
Measure of Variation		

E-mail office@phuse.global

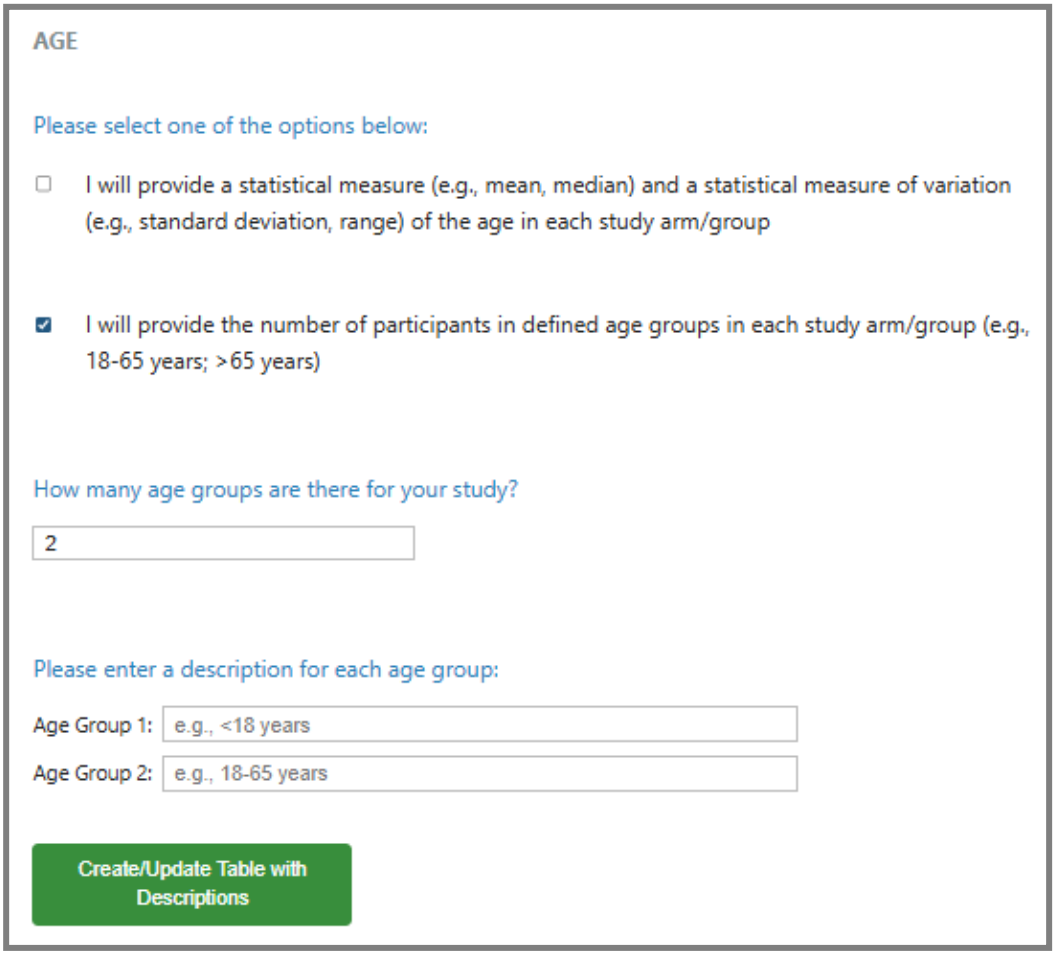
Web www.phuse.global

PHUSE Limited
Company No: 05422297
VAT No: GB920 0529 64

PHUSE CTR
(wholly owned European subsidiary of PHUSE Limited)
Company No: 750562

PHUSE India Private Limited
Corporate Identity No: U82300PN2024FTC236151
GST No: 27AAPCP2555B1ZE
PAN No: AAPCP2555B

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ



Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

AGE

Please select one of the options below:

- [ ] I will provide a statistical measure (e.g., mean, median) and a statistical measure of variation (e.g., standard deviation, range) of the age in each study arm/group
- [x] I will provide the number of participants in defined age groups in each study arm/group (e.g., 18-65 years; >65 years)

How many age groups are there for your study?

2

Please enter a description for each age group:

Age Group 1: e.g., <18 years

Age Group 2: e.g., 18-65 years

Create/Update Table with Descriptions

Other Population

Please complete the table below:

Age Data	Arm/Group 1	Arm/Group 2
Number of Participants with Available Data at Baseline	0	0
<18 years - Number of Participants	0	0
18-65 years - Number of Participants	0	0

E-mail office@phuse.global

Web www.phuse.global

PHUSE Limited
Company No: 05422297
VAT No: GB920 0529 64

PHUSE CTR
(wholly owned European subsidiary of PHUSE Limited)
Company No: 750562

PHUSE India Private Limited
Corporate Identity No: U82300PN2024FTC236151
GST No: 27AAPCP2555B1ZE
PAN No: AAPCP2555B

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

Additional Population 2

Delete Population 2

BASELINE PARTICIPANT CHARACTERISTICS - POPULATION 2

The World Health Organisation (WHO) requires that baseline characteristics for age, sex and other relevant characteristics are included in registry summary results

This is typically for all participants allocated to study arms/groups

After entering information for this study population, you will have the option to enter baseline characteristics for another study population where this would help others understand your study

For multi-part studies, to provide baseline characteristics for different parts of your study enter each part in turn as a different population. Select Other from the dropdown box below and provide a part description and the population e.g., Dose Ranging Part. Intent-to-Treat Population (all participants allocated to study arms/groups)

Please select the population for baseline characteristics from the dropdown list:

Please select...

Please select one of the options below:

☐ I will upload baseline participant characteristics table(s) for this study population in .pdf format

ⓘ Select this option if it is difficult to use the registry tables to describe baseline characteristics for your study or if it is easier to provide accurate and complete data.

☐ I will provide baseline participant characteristics for this study population by completing registry tables

Check Your Submission

Please select the population for baseline characteristics from the dropdown list:

Please select...

- Please select...
- Intent-to-treat population (all participants as allocated to study arms/groups)
- Per-protocol population (only participants who complied with the protocol)
- Safety population (all participants who received at least one dose)
- Other

E-mail office@phuse.global

Web www.phuse.global

PHUSE Limited
Company No: 05422297
VAT No: GB920 0529 64

PHUSE CTR
(wholly owned European subsidiary of PHUSE Limited)
Company No: 750562

PHUSE India Private Limited
Corporate Identity No: U82300PN2024FTC236151
GST No: 27AAPCP2555B1ZE
PAN No: AAPCP2555B

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

Outcome Measures – Population 1:

WHO requirement: Primary and secondary outcome measure results are included in the registry summary results.

Please help us improve this form by providing feedback on this section:

1. How easy will it be to complete this section?

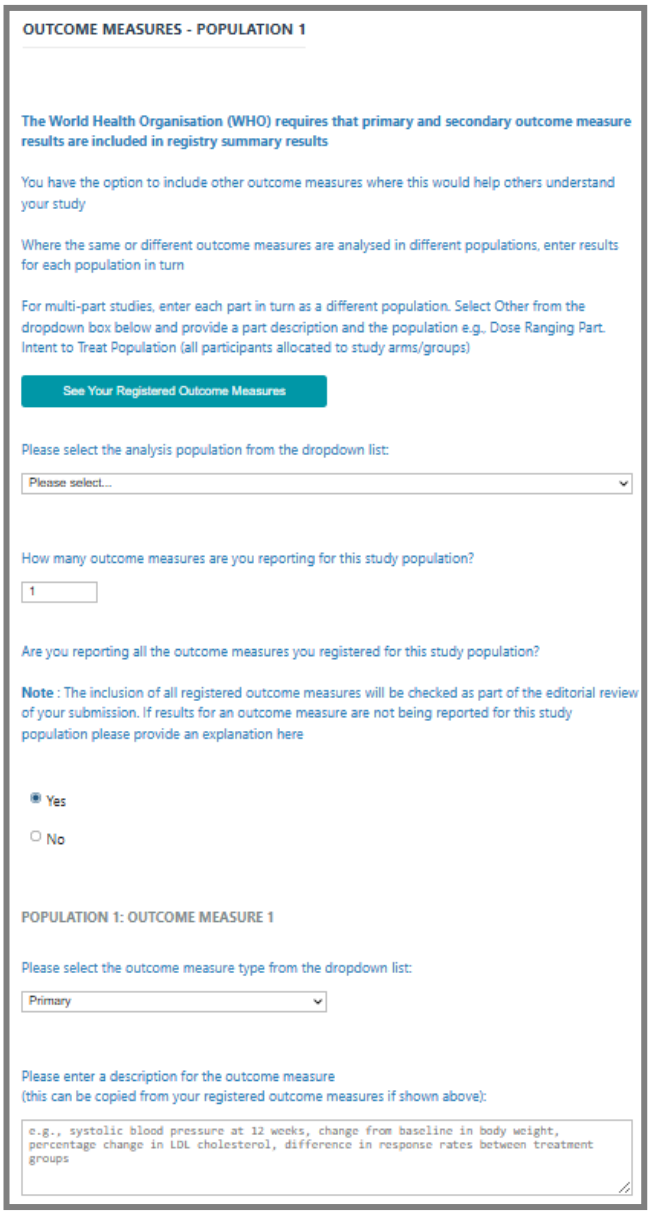
Very easy | **Moderately easy** | **Not easy**

PHUSE Response Selection:
Not easy

2. What suggestions would you make to improve this section?

- In the section for uploading of results, is that needed for individual endpoints or for all of them?
- Clarification is required on how to report the outcome measure for a different population when a different population was selected for the overall Outcome Measures section. This is a system limitation in reporting outcome measures for different populations, whereby only one population can be selected per outcome measure, which may not reflect study complexity.

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ



OUTCOME MEASURES - POPULATION 1

The World Health Organisation (WHO) requires that primary and secondary outcome measure results are included in registry summary results

You have the option to include other outcome measures where this would help others understand your study

Where the same or different outcome measures are analysed in different populations, enter results for each population in turn

For multi-part studies, enter each part in turn as a different population. Select Other from the dropdown box below and provide a part description and the population e.g., Dose Ranging Part. Intent to Treat Population (all participants allocated to study arms/groups)

See Your Registered Outcome Measures

Please select the analysis population from the dropdown list:

Please select...

How many outcome measures are you reporting for this study population?

1

Are you reporting all the outcome measures you registered for this study population?

Note : The inclusion of all registered outcome measures will be checked as part of the editorial review of your submission. If results for an outcome measure are not being reported for this study population please provide an explanation here

Yes

No

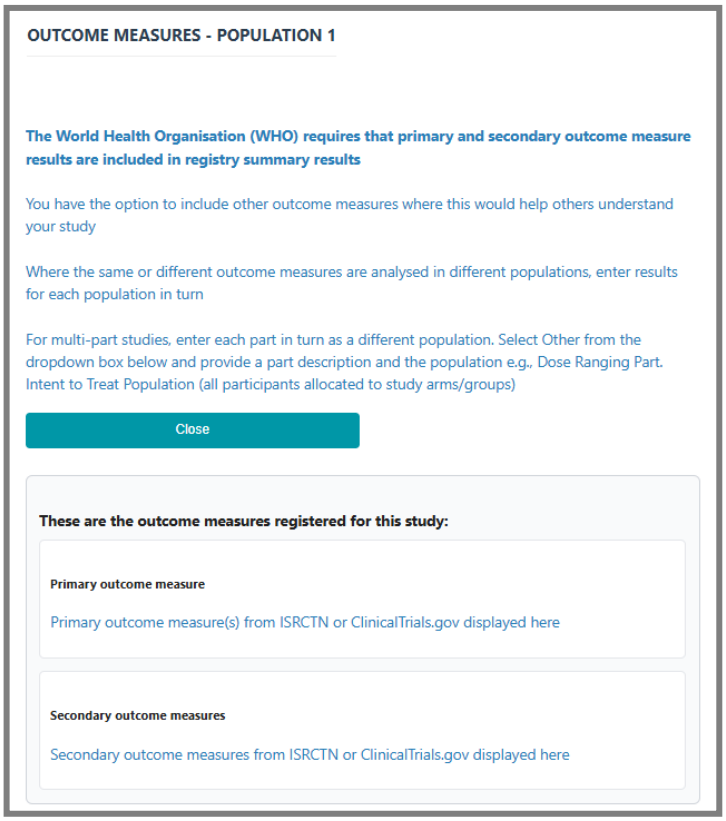
POPULATION 1: OUTCOME MEASURE 1

Please select the outcome measure type from the dropdown list:

Primary

Please enter a description for the outcome measure
(this can be copied from your registered outcome measures if shown above):

e.g., systolic blood pressure at 12 weeks, change from baseline in body weight, percentage change in LDL cholesterol, difference in response rates between treatment groups



OUTCOME MEASURES - POPULATION 1

The World Health Organisation (WHO) requires that primary and secondary outcome measure results are included in registry summary results

You have the option to include other outcome measures where this would help others understand your study

Where the same or different outcome measures are analysed in different populations, enter results for each population in turn

For multi-part studies, enter each part in turn as a different population. Select Other from the dropdown box below and provide a part description and the population e.g., Dose Ranging Part. Intent to Treat Population (all participants allocated to study arms/groups)

Close

These are the outcome measures registered for this study:

Primary outcome measure

Primary outcome measure(s) from ISRCTN or ClinicalTrials.gov displayed here

Secondary outcome measures

Secondary outcome measures from ISRCTN or ClinicalTrials.gov displayed here

E-mail office@phuse.global

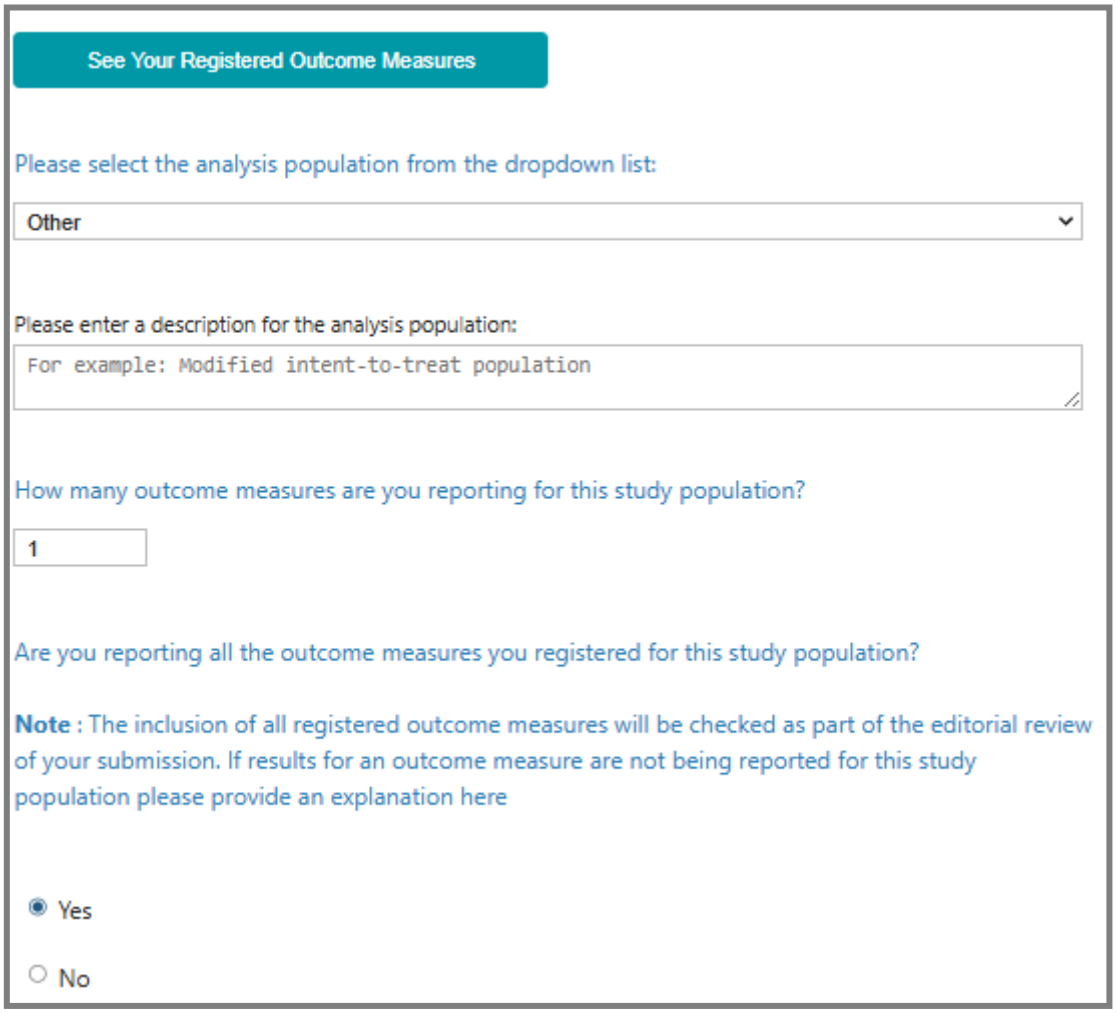
Web www.phuse.global

PHUSE Limited
Company No: 05422297
VAT No: GB920 0529 64

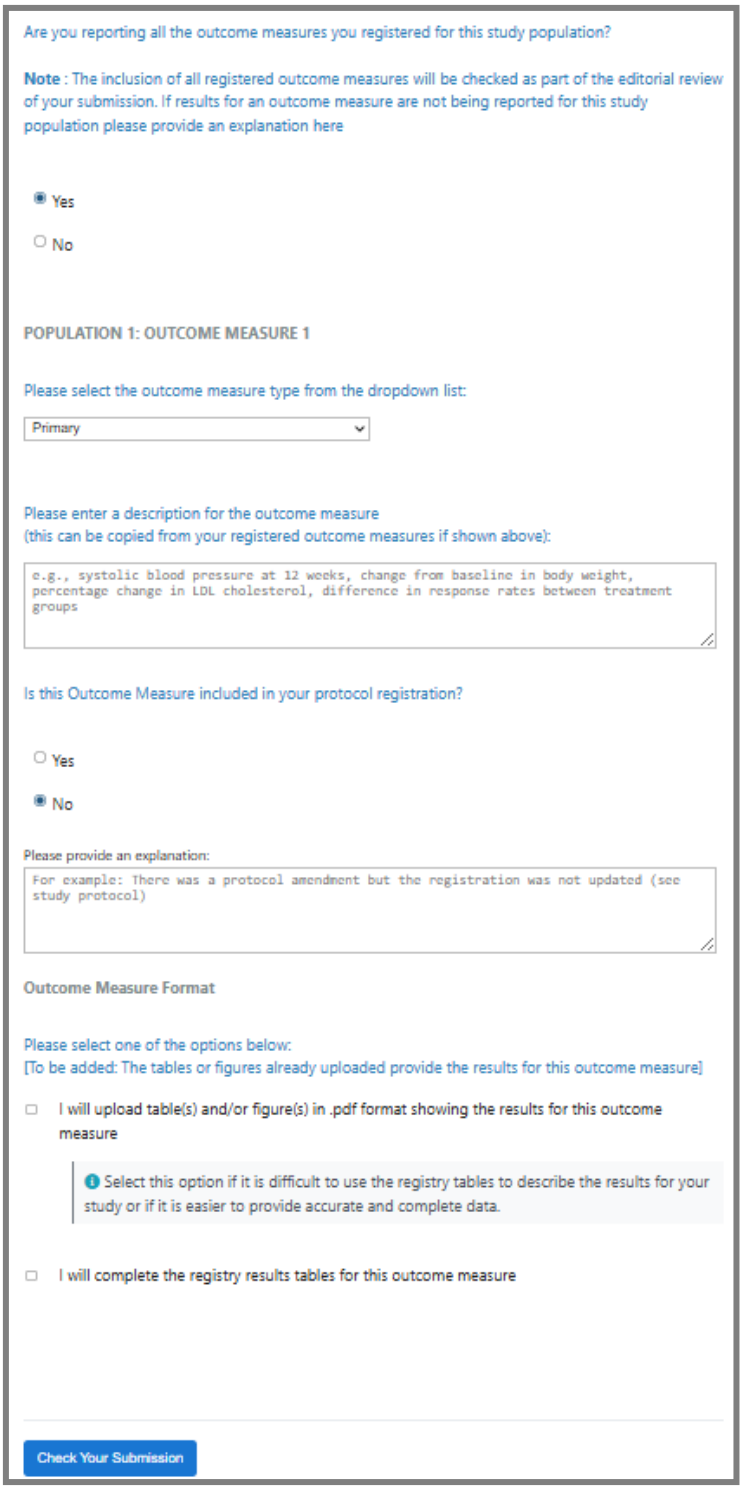
PHUSE CTR
(wholly owned European subsidiary of PHUSE Limited)
Company No: 750562

PHUSE India Private Limited
Corporate Identity No: U82300PN2024FTC236151
GST No: 27AAPCP2555B1ZE
PAN No: AAPCP2555B

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ



Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ



E-mail office@phuse.global

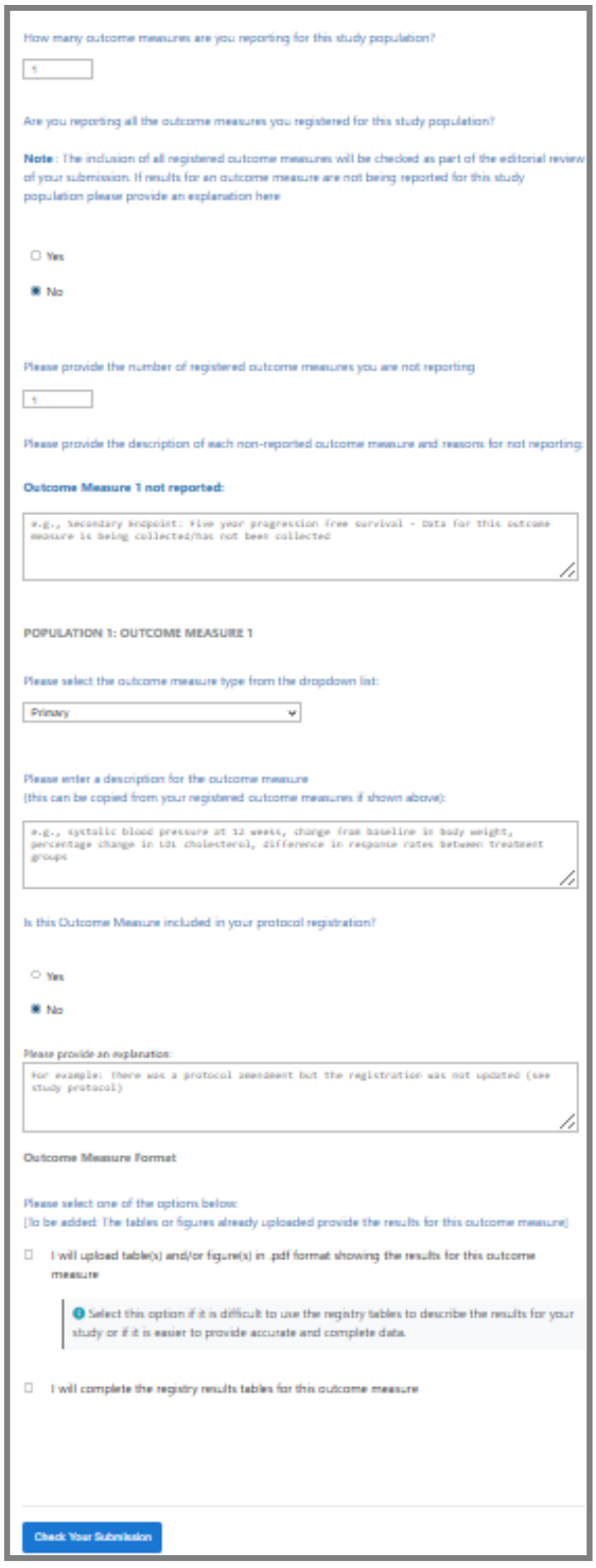
Web www.phuse.global

PHUSE Limited
Company No: 05422297
VAT No: GB920 0529 64

PHUSE CTR
(wholly owned European subsidiary of PHUSE Limited)
Company No: 750562

PHUSE India Private Limited
Corporate Identity No: U82300PN2024FTC236151
GST No: 27AAPCP2555B1ZE
PAN No: AAPCP2555B

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ



How many outcome measures are you reporting for this study population?

1

Are you reporting all the outcome measures you registered for this study population?

Note: The inclusion of all registered outcome measures will be checked as part of the editorial review of your submission. If results for an outcome measure are not being reported for this study population please provide an explanation here

- ☐ Yes
- ◉ No

Please provide the number of registered outcome measures you are not reporting

1

Please provide the description of each non-reported outcome measure and reasons for not reporting:

Outcome Measure 1 not reported:

e.g., Secondary Endpoint: Five year progression free survival - Data for this outcome measure is being collected/has not been collected

POPULATION 1: OUTCOME MEASURE 1

Please select the outcome measure type from the dropdown list:

Primary

Please enter a description for the outcome measure
(this can be copied from your registered outcome measures if shown above):

e.g., systolic blood pressure at 12 weeks, change from baseline in body weight, percentage change in LDL cholesterol, difference in response rates between treatment groups

Is this Outcome Measure included in your protocol registration?

- ○ Yes
- ◉ No

Please provide an explanation:

For example: there was a protocol amendment but the registration was not updated (see study protocol)

Outcome Measure Format

Please select one of the options below:
[To be added: The tables or figures already uploaded provide the results for this outcome measure]

- ☐ I will upload table(s) and/or figure(s) in .pdf format showing the results for this outcome measure

  ⓘ Select this option if it is difficult to use the registry tables to describe the results for your study or if it is easier to provide accurate and complete data.

- ☐ I will complete the registry results tables for this outcome measure

Check Your Submission

E-mail office@phuse.global

Web www.phuse.global

PHUSE Limited
Company No: 05422297
VAT No: GB920 0529 64

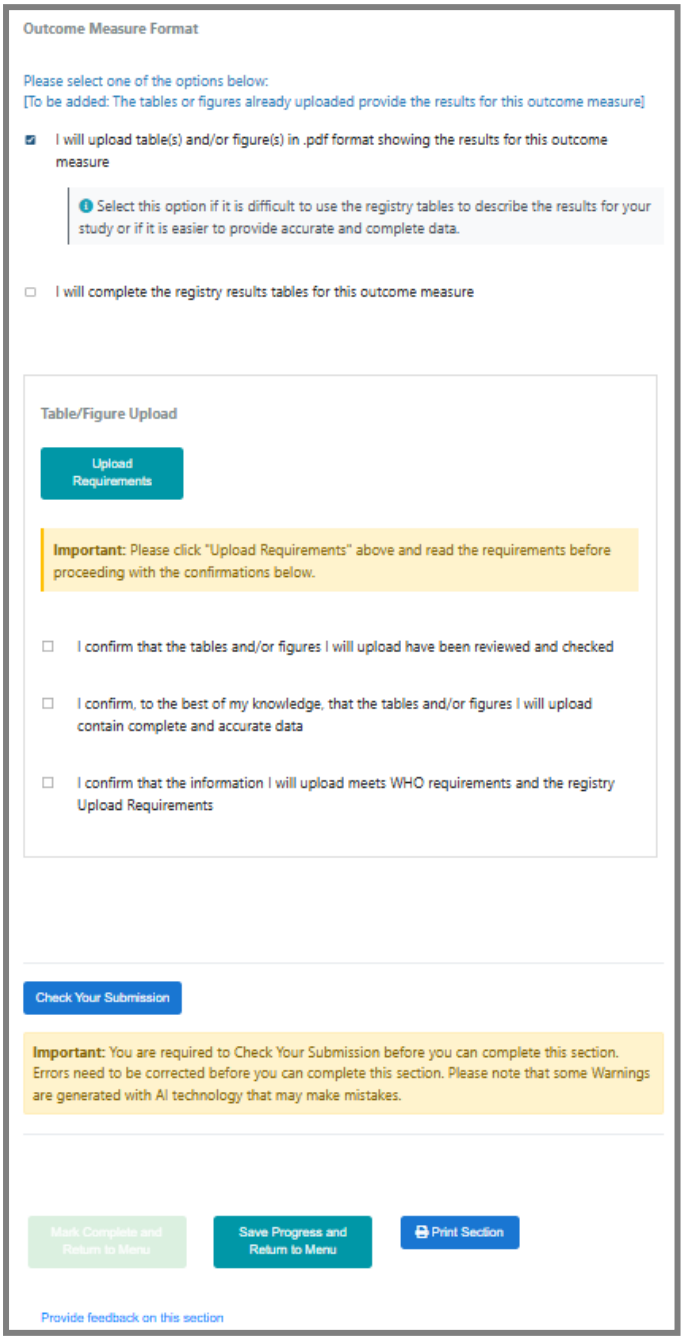
PHUSE CTR
(wholly owned European subsidiary of PHUSE Limited)
Company No: 750562

PHUSE India Private Limited
Corporate Identity No: U82300PN2024FTC236151
GST No: 27AAPCP2555B1ZE
PAN No: AAPCP2555B

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

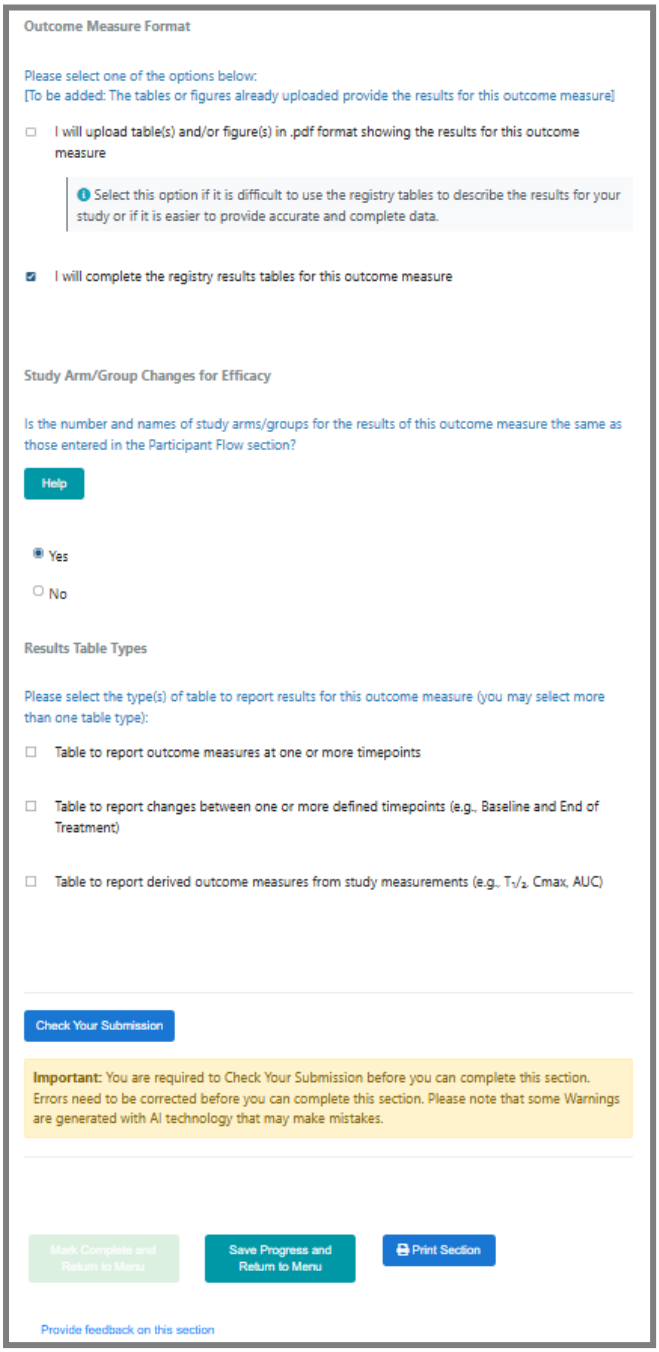
Options:

PDF UPLOAD



Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

REGISTRY RESULTS TABLES UPLOAD



Outcome Measure Format

Please select one of the options below:
[To be added: The tables or figures already uploaded provide the results for this outcome measure]

☐ I will upload table(s) and/or figure(s) in .pdf format showing the results for this outcome measure

ⓘ Select this option if it is difficult to use the registry tables to describe the results for your study or if it is easier to provide accurate and complete data.

☑ I will complete the registry results tables for this outcome measure

Study Arm/Group Changes for Efficacy

Is the number and names of study arms/groups for the results of this outcome measure the same as those entered in the Participant Flow section?

Help

◉ Yes

○ No

Results Table Types

Please select the type(s) of table to report results for this outcome measure (you may select more than one table type):

☐ Table to report outcome measures at one or more timepoints

☐ Table to report changes between one or more defined timepoints (e.g., Baseline and End of Treatment)

☐ Table to report derived outcome measures from study measurements (e.g., $T_{1/2}$, Cmax, AUC)

Check Your Submission

Important: You are required to Check Your Submission before you can complete this section. Errors need to be corrected before you can complete this section. Please note that some Warnings are generated with AI technology that may make mistakes.

Mark Complete and Return to Menu | Save Progress and Return to Menu | Print Section

Provide feedback on this section

E-mail office@phuse.global

Web www.phuse.global

PHUSE Limited
Company No: 05422297
VAT No: GB920 0529 64

PHUSE CTR
(wholly owned European subsidiary of PHUSE Limited)
Company No: 750562

PHUSE India Private Limited
Corporate Identity No: U82300PN2024FTC236151
GST No: 27AAPCP2555B1ZE
PAN No: AAPCP2555B

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

Is this Outcome Measure included in your protocol registration?

- ○ Yes
- ◉ No

Please provide an explanation:

For example: There was a protocol amendment but the registration was not updated (see study protocol)

Outcome Measure Format

Please select one of the options below:
[To be added: The tables or figures already uploaded provide the results for this outcome measure]

- ☐ I will upload table(s) and/or figure(s) in .pdf format showing the results for this outcome measure

> ℹ Select this option if it is difficult to use the registry tables to describe the results for your study or if it is easier to provide accurate and complete data.

- ☐ I will complete the registry results tables for this outcome measure

Check Your Submission

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

Adverse Events – Population 1:

WHO requirement: Adverse events (AEs) for all-cause mortality (death), serious adverse events and other adverse events are included in the registry summary results.

Please help us improve this form by providing feedback on this section:

1. How easy will it be to complete this section?

Very easy | **Moderately easy** | **Not easy**

PHUSE Response Selection:
Not easy

2. What suggestions would you make to improve this section?

- Adverse Events for Another Population:

  "Do you want to add adverse events for another study population?
  (The WHO does not require that additional populations are included in registry summary results.)"

  Clarification required here – is this talking about any sub study or something else?

- The terms "another study population" and "additional populations" should be defined in the form to avoid ambiguity.

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

ADVERSE EVENTS - POPULATION 1

The World Health Organisation (WHO) requires that adverse events (AEs) for all cause mortality (death), serious adverse events and other adverse events are included in registry summary results

Close

Definitions

Adverse Event (AE)

Any untoward medical occurrence in a patient or clinical investigation subject administered a treatment (e.g., a pharmaceutical product) and which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a treatment, whether or not related to the treatment.

Serious Adverse Event (SAE)

Any untoward medical occurrence that at any dose:

- results in death,
- is life-threatening,
- requires inpatient hospitalisation or prolongation of existing hospitalisation,
- results in persistent or significant disability/incapacity, or
- is a congenital anomaly/birth defect.

Medical and scientific judgment should be exercised in deciding whether other situations should be considered serious adverse events, such as important medical events that may not be immediately life-threatening or result in death or hospitalisation but may jeopardise the patient or may require intervention to prevent one of the other outcomes listed.

Adverse Event Data Collection

Please provide a description for how adverse event data were collected and assessed (optional):

e.g., systematic such as recorded on a case report form or non-systematic such as passive self reporting

Please provide the adverse event dictionary or vocabulary used (optional):

e.g., SNOMED CT, MedDRA (12.0)

After entering information for this study population, you will have the option to enter adverse events for another study population where this would help others understand your study

For multi-part studies, to provide adverse events for different parts of your study enter each part in turn as a different population. Select Other from the dropdown box below and provide a part description and the population e.g., Dose Ranging Part. Intent to Treat Population (all participants allocated to study arms/groups)

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

Population for Adverse Events

Please select the population used for adverse event reporting:

Please select...

Time Periods for Adverse Event Reporting

How many time periods for AE reporting do you want to include for this population?
(Note: In this prototype changing the number of time periods after entering table data will reset the tables)

Number of time periods: 1

Time Period 1

Please describe the time period for AE reporting:

e.g., on treatment plus 6 months follow-up

Study Arm/Group Changes for Safety

Is the number and names of study arms/groups the same as you entered in the Participant Flow section?

Close

The study arm/group names may be different compared with those you entered in the Participant Flow section.

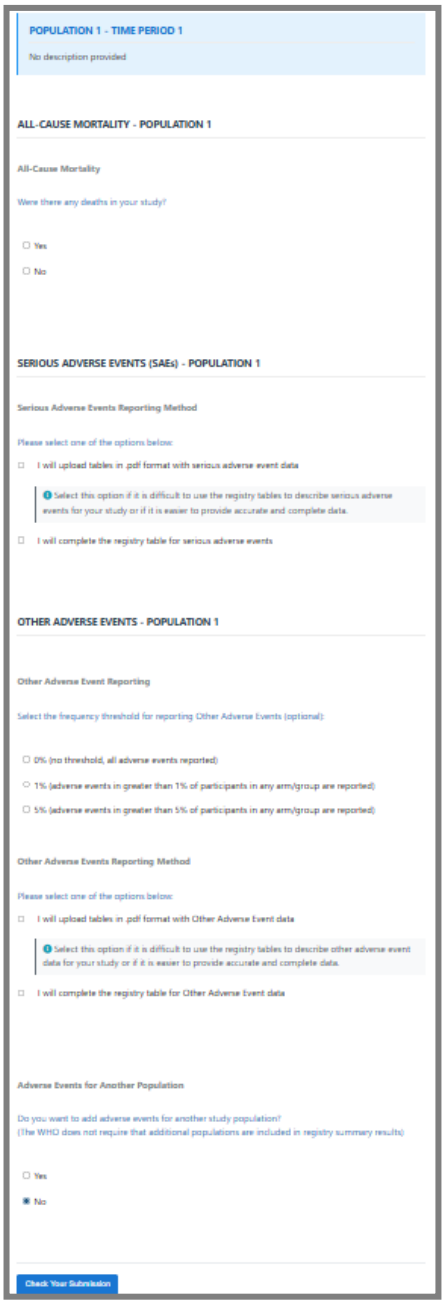
For example, a cross-over trial may have two study groups:

- Group 1: Active Treatment followed by Placebo
- Group 2: Placebo followed by Active Treatment

For the assessment of adverse events, participants who received the Active Treatment may be compared with participants who received Placebo.

- (•) Yes
- ( ) No

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ



E-mail office@phuse.global

Web www.phuse.global

PHUSE Limited
Company No: 05422297
VAT No: GB920 0529 64

PHUSE CTR
(wholly owned European subsidiary of PHUSE Limited)
Company No: 750562

PHUSE India Private Limited
Corporate Identity No: U82300PN2024FTC236151
GST No: 27AAPCP2555B1ZE
PAN No: AAPCP2555B

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

Study Conclusion:

(Optional Field) The WHO does not require study limitations or a study conclusion to be included in the registry summary results.

Please help us improve this form by providing feedback on this section:

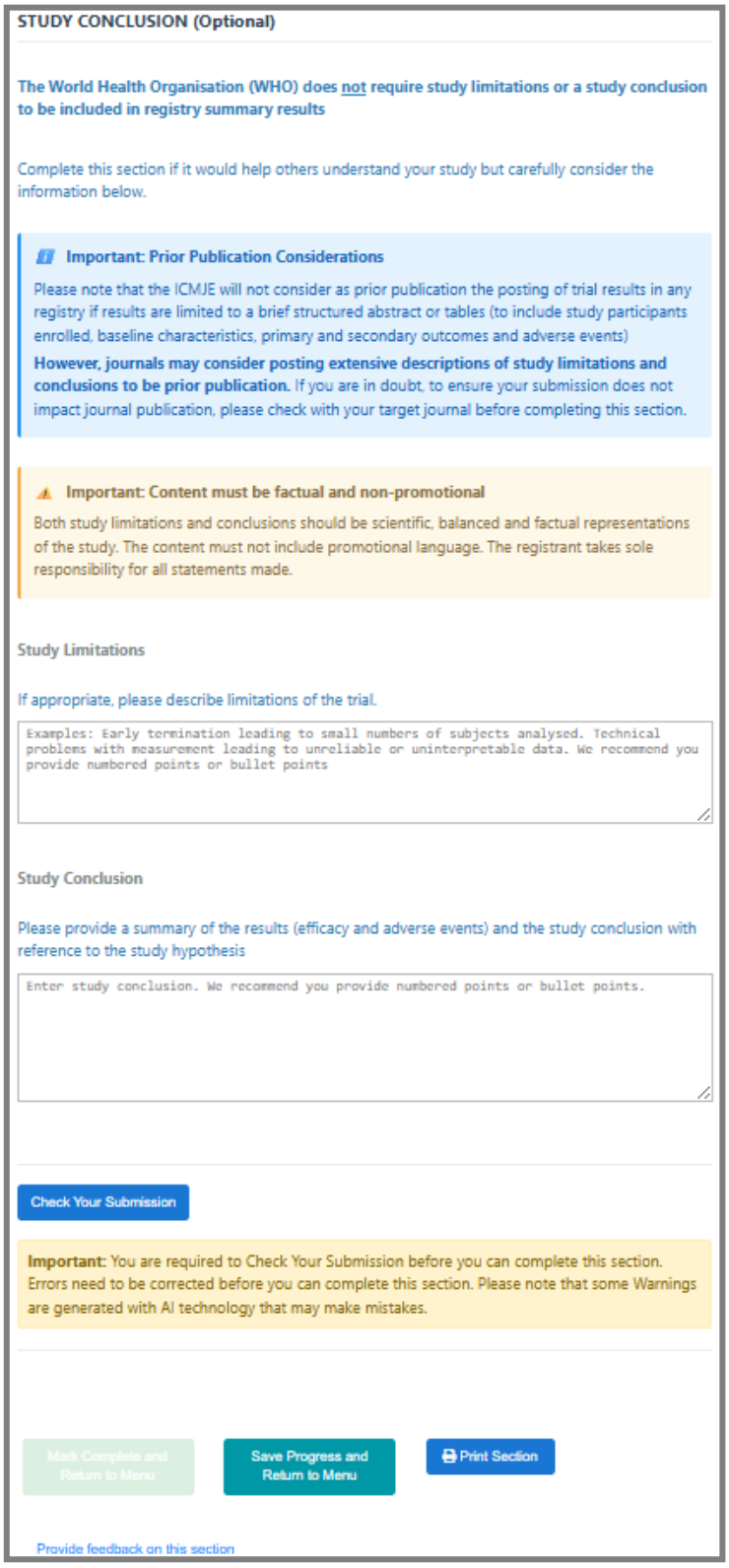
1. How easy will it be to complete this section?

Very easy | **Moderately easy** | **Not easy**

PHUSE Response Selection:
Moderately easy

2. What suggestions would you make to improve this section?

No comments



E-mail office@phuse.global

Web www.phuse.global

PHUSE Limited
Company No: 05422297
VAT No: GB920 0529 64

PHUSE CTR
(wholly owned European subsidiary of PHUSE Limited)
Company No: 750562

PHUSE India Private Limited
Corporate Identity No: U82300PN2024FTC236151
GST No: 27AAPCP2555B1ZE
PAN No: AAPCP2555B

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

Share Reusable Data:

Have you uploaded (or do you intend to upload) one or more PDF files of your results in any of the following sections: Participant Flow, Baseline Characteristics, Outcome Measures, Statistical Results or Adverse Events?

Please help us improve this form by providing feedback on this section:

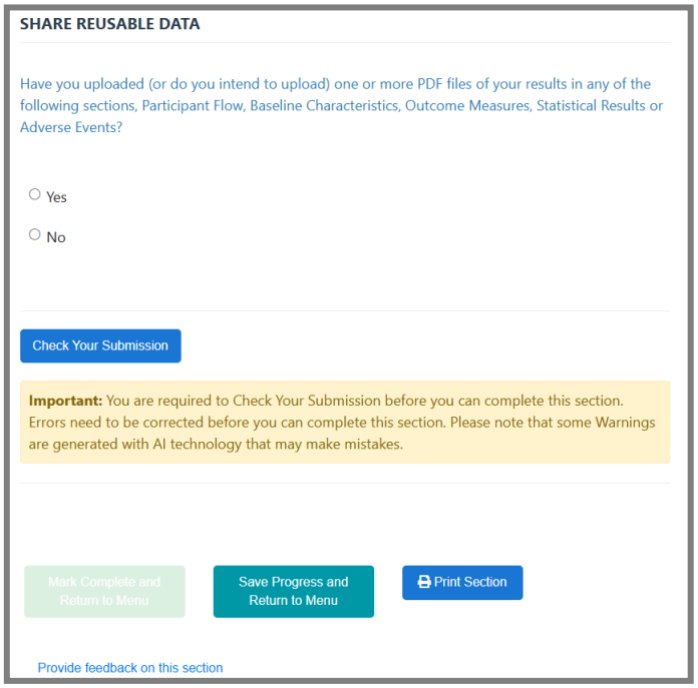
1. How easy will it be to complete this section?

Very easy | **Moderately easy** | **Not easy**

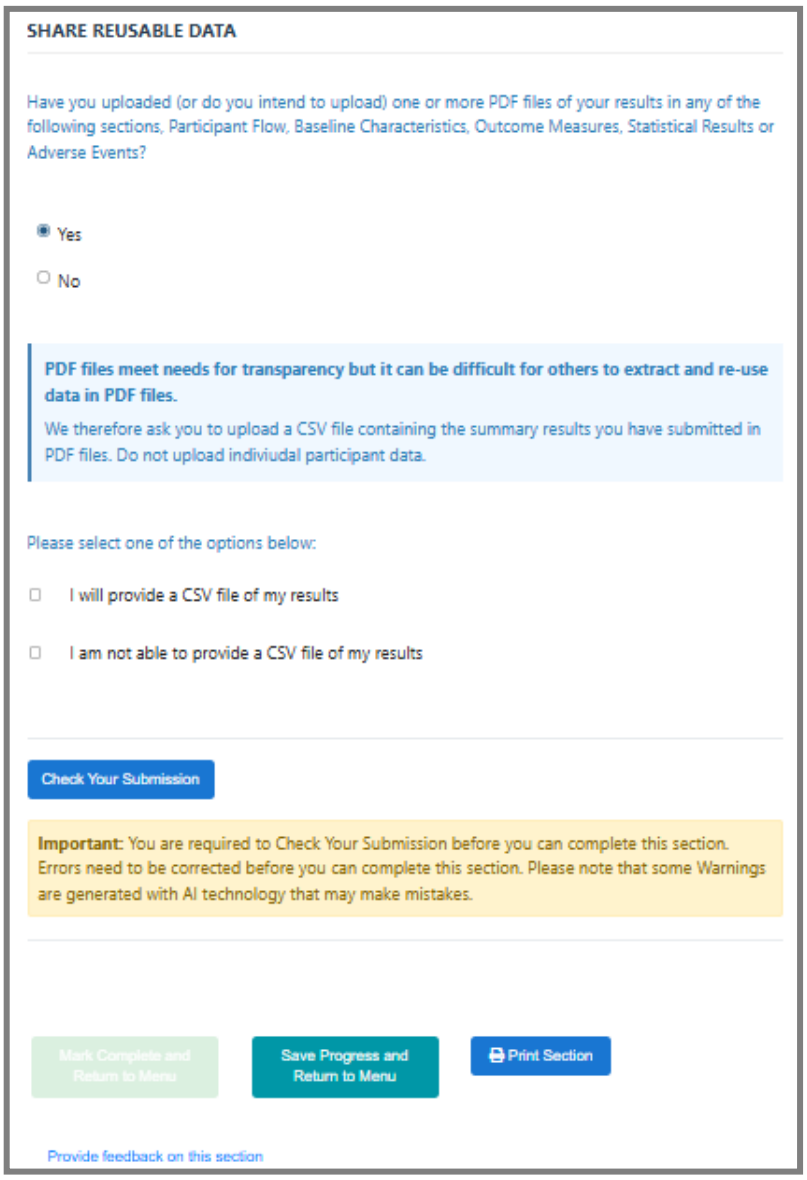
PHUSE Response Selection:
Not easy

2. What suggestions would you make to improve this section?

- PDF vs. CSV file uploading should be noted in individual sections where applicable. Currently, CSV uploads are only mentioned towards the end of the form within the 'Share Reusable Data' section. We recommend being more specific earlier on so users know before they reach the final section.



Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ



SHARE REUSABLE DATA

Have you uploaded (or do you intend to upload) one or more PDF files of your results in any of the following sections, Participant Flow, Baseline Characteristics, Outcome Measures, Statistical Results or Adverse Events?

(•) Yes

( ) No

PDF files meet needs for transparency but it can be difficult for others to extract and re-use data in PDF files.

We therefore ask you to upload a CSV file containing the summary results you have submitted in PDF files. Do not upload indiviudal participant data.

Please select one of the options below:

☐ I will provide a CSV file of my results

☐ I am not able to provide a CSV file of my results

Check Your Submission

Important: You are required to Check Your Submission before you can complete this section. Errors need to be corrected before you can complete this section. Please note that some Warnings are generated with AI technology that may make mistakes.

Mark Complete and Return to Menu | Save Progress and Return to Menu | Print Section

Provide feedback on this section

E-mail office@phuse.global

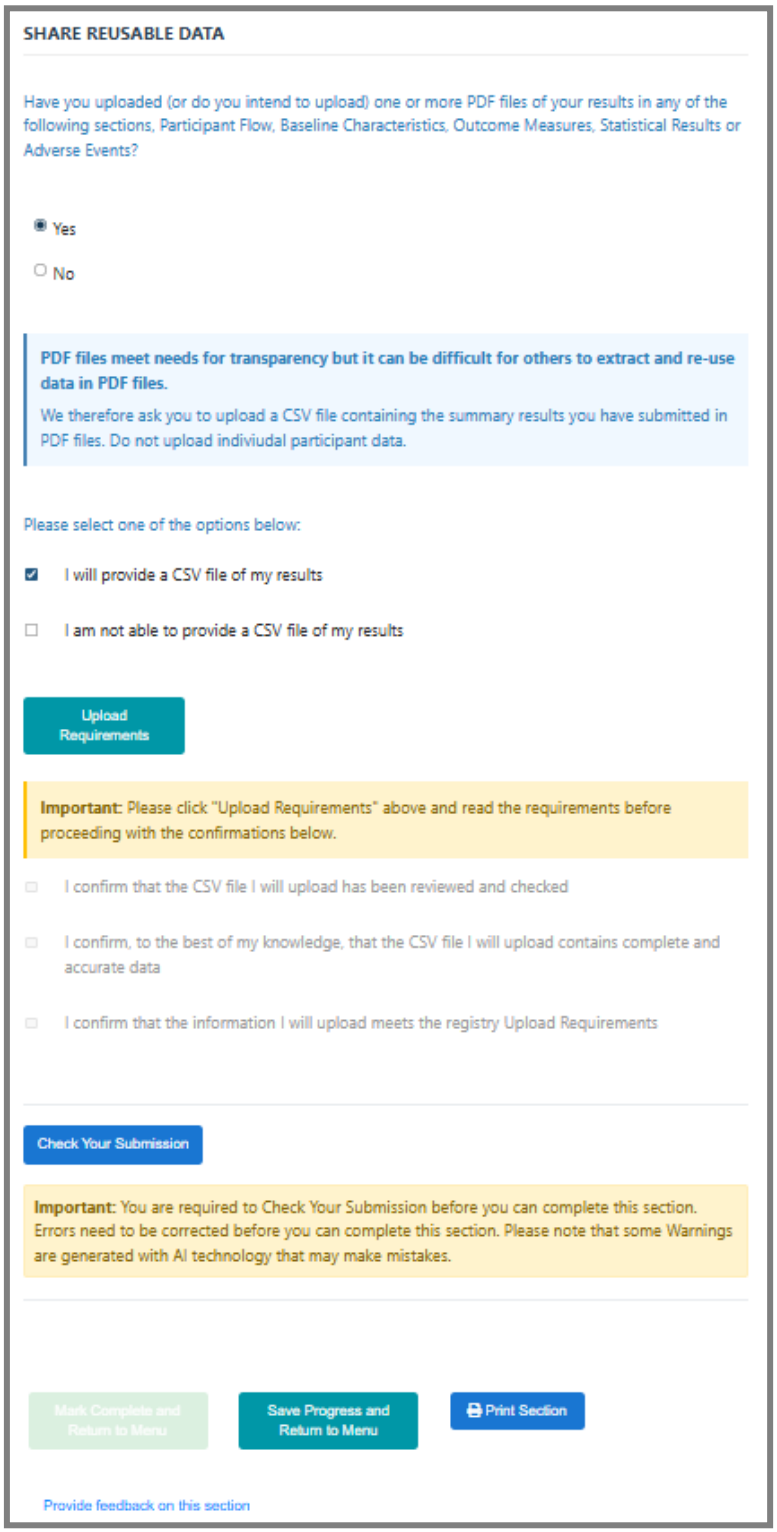
Web www.phuse.global

PHUSE Limited
Company No: 05422297
VAT No: GB920 0529 64

PHUSE CTR
(wholly owned European subsidiary of PHUSE Limited)
Company No: 750562

PHUSE India Private Limited
Corporate Identity No: U82300PN2024FTC236151
GST No: 27AAPCP2555B1ZE
PAN No: AAPCP2555B

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ



SHARE REUSABLE DATA

Have you uploaded (or do you intend to upload) one or more PDF files of your results in any of the following sections, Participant Flow, Baseline Characteristics, Outcome Measures, Statistical Results or Adverse Events?

(•) Yes

( ) No

PDF files meet needs for transparency but it can be difficult for others to extract and re-use data in PDF files.

We therefore ask you to upload a CSV file containing the summary results you have submitted in PDF files. Do not upload indiviudal participant data.

Please select one of the options below:

[x] I will provide a CSV file of my results

[ ] I am not able to provide a CSV file of my results

Upload Requirements

Important: Please click "Upload Requirements" above and read the requirements before proceeding with the confirmations below.

[ ] I confirm that the CSV file I will upload has been reviewed and checked

[ ] I confirm, to the best of my knowledge, that the CSV file I will upload contains complete and accurate data

[ ] I confirm that the information I will upload meets the registry Upload Requirements

Check Your Submission

Important: You are required to Check Your Submission before you can complete this section. Errors need to be corrected before you can complete this section. Please note that some Warnings are generated with AI technology that may make mistakes.

Mark Complete and Return to Menu | Save Progress and Return to Menu | Print Section

Provide feedback on this section

E-mail office@phuse.global

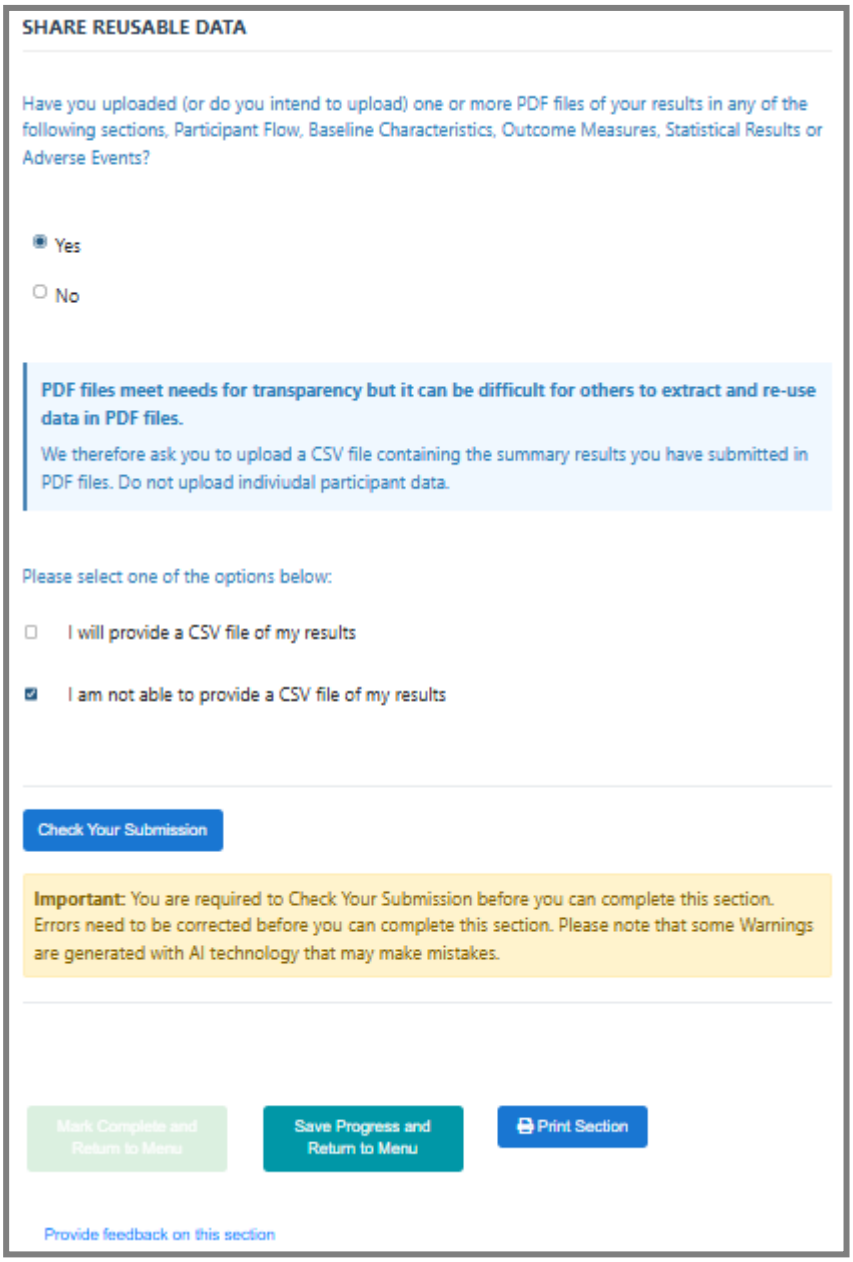
Web www.phuse.global

PHUSE Limited
Company No: 05422297
VAT No: GB920 0529 64

PHUSE CTR
(wholly owned European subsidiary of PHUSE Limited)
Company No: 750562

PHUSE India Private Limited
Corporate Identity No: U82300PN2024FTC236151
GST No: 27AAPCP2555B1ZE
PAN No: AAPCP2555B

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ



E-mail office@phuse.global

Web www.phuse.global

PHUSE Limited
Company No: 05422297
VAT No: GB920 0529 64

PHUSE CTR
(wholly owned European subsidiary of PHUSE Limited)
Company No: 750562

PHUSE India Private Limited
Corporate Identity No: U82300PN2024FTC236151
GST No: 27AAPCP2555B1ZE
PAN No: AAPCP2555B

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

SHARE REUSABLE DATA

Have you uploaded (or do you intend to upload) one or more PDF files of your results in any of the following sections, Participant Flow, Baseline Characteristics, Outcome Measures, Statistical Results or Adverse Events?

- ○ Yes
- ◉ No

As you have completed registry tables the data you have provided can be easily extracted and re-used.

Check Your Submission

Important: You are required to Check Your Submission before you can complete this section. Errors need to be corrected before you can complete this section. Please note that some Warnings are generated with AI technology that may make mistakes.

Mark Complete and Return to Menu | Save Progress and Return to Menu | Print Section

Provide feedback on this section

E-mail office@phuse.global

Web www.phuse.global

PHUSE Limited
Company No: 05422297
VAT No: GB920 0529 64

PHUSE CTR
(wholly owned European subsidiary of PHUSE Limited)
Company No: 750562

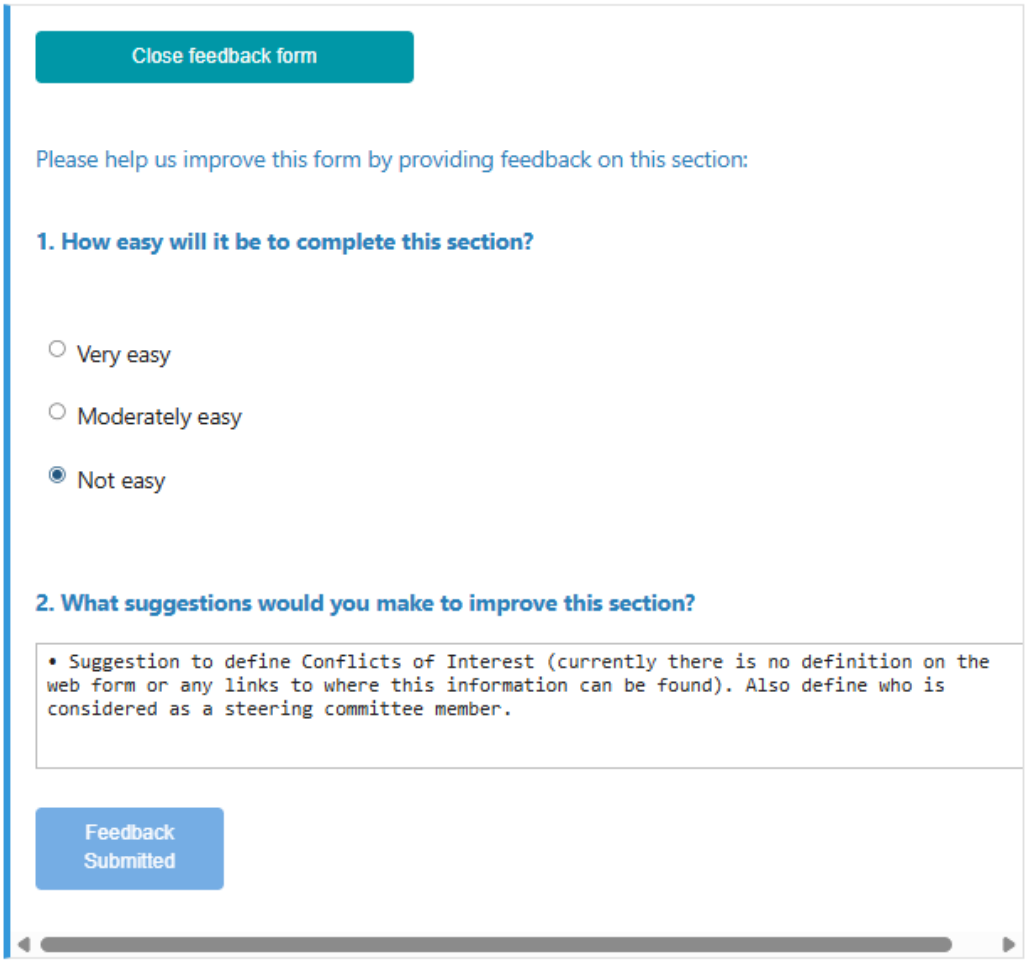
PHUSE India Private Limited
Corporate Identity No: U82300PN2024FTC236151
GST No: 27AAPCP2555B1ZE
PAN No: AAPCP2555B

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

Submission confirmation denoted by 'Feedback Submitted' for each section:

POTENTIAL CONFLICTS OF INTEREST

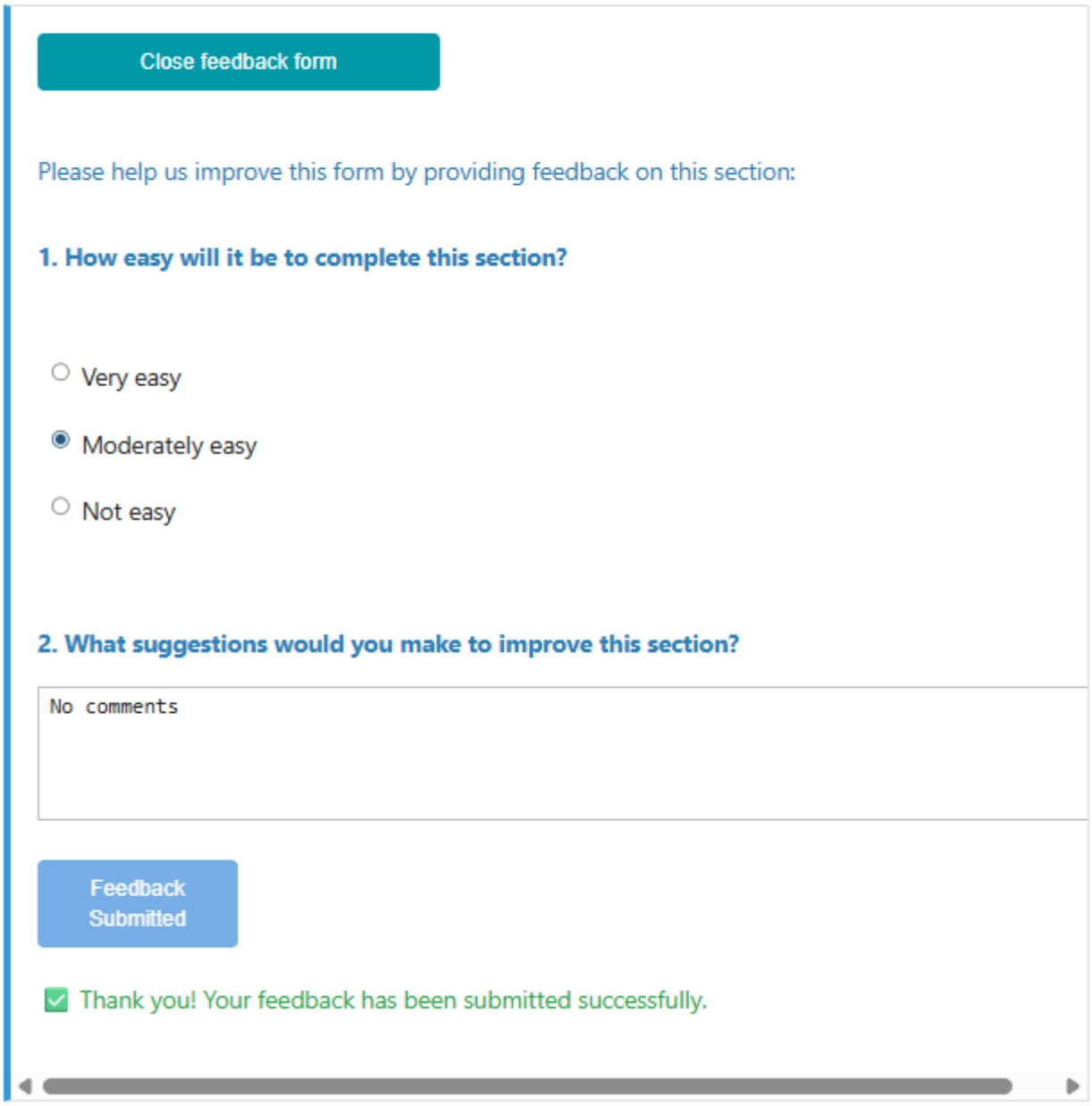
Close feedback form



Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

PROTOCOL & STATISTICAL ANALYSIS PLAN

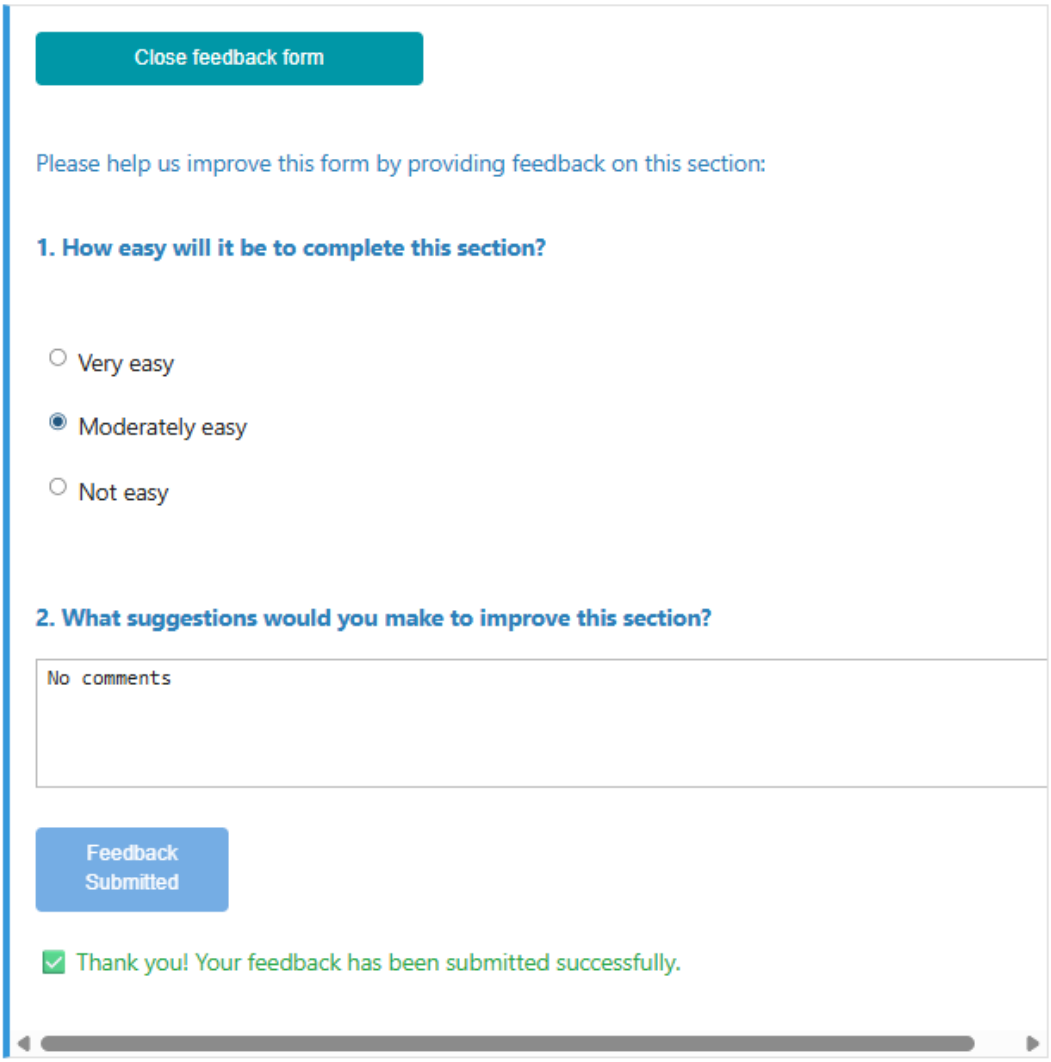
Close feedback form



Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

COMPLETION STATUS

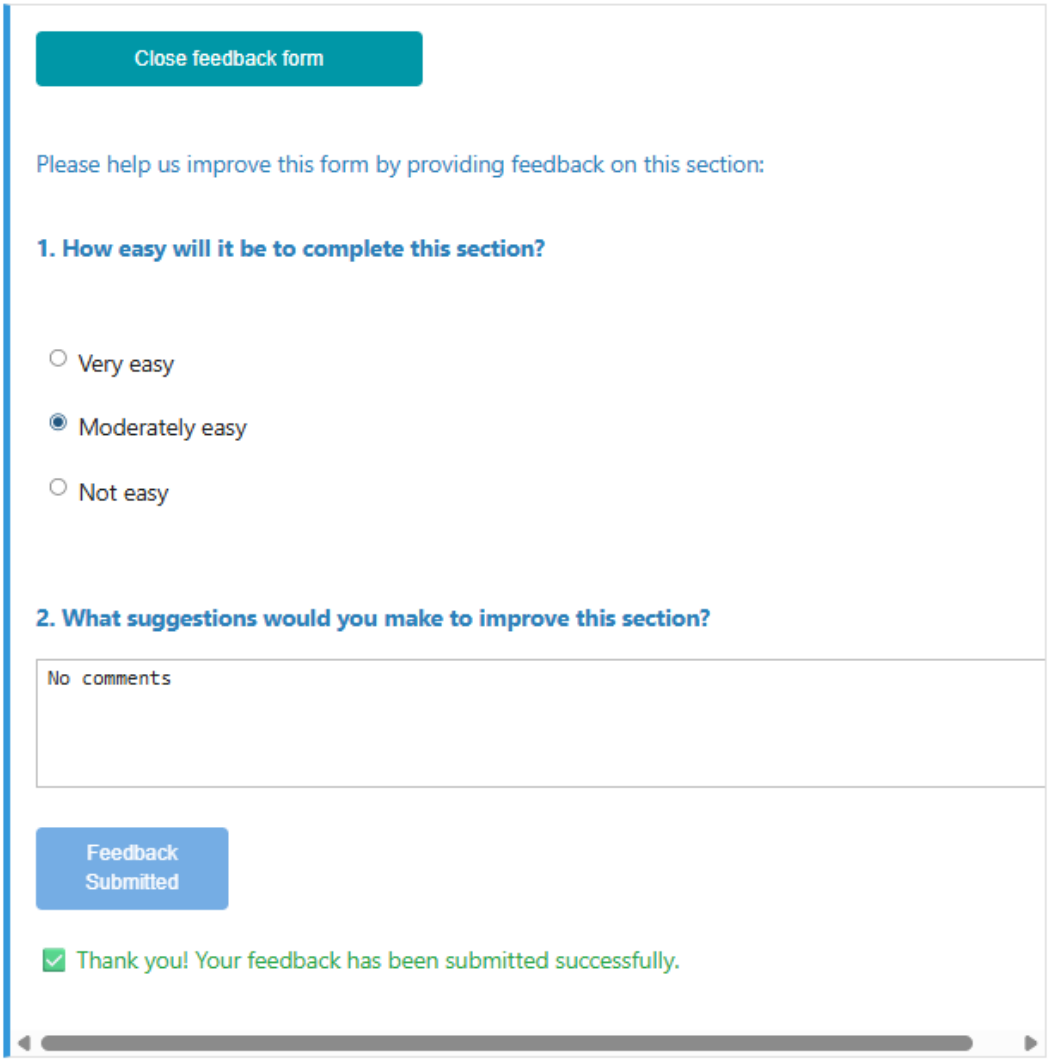
Close feedback form



Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

PUBLICATION STATUS

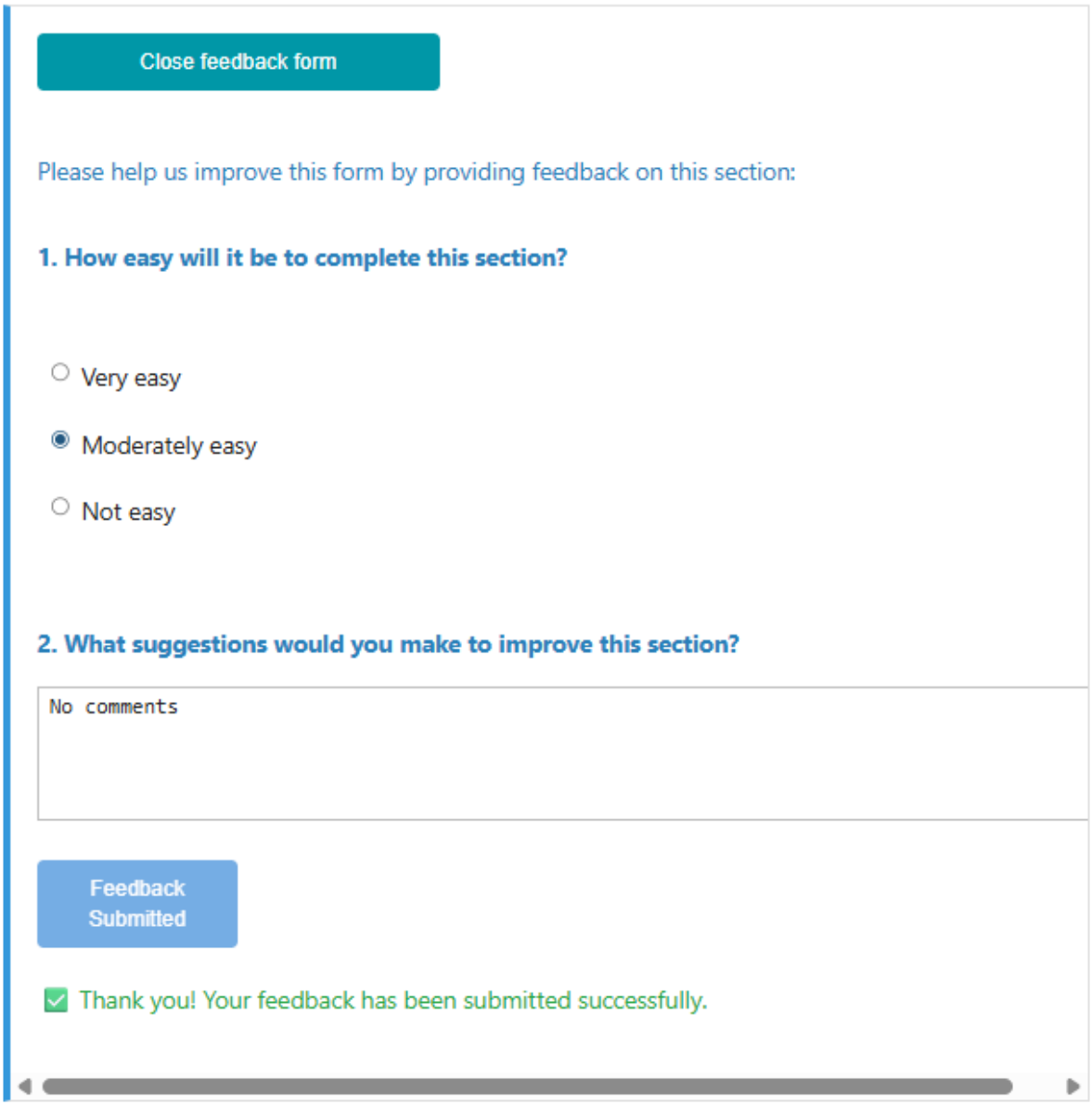
Close feedback form



Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

PLAIN LANGUAGE SUMMARY OF RESULTS

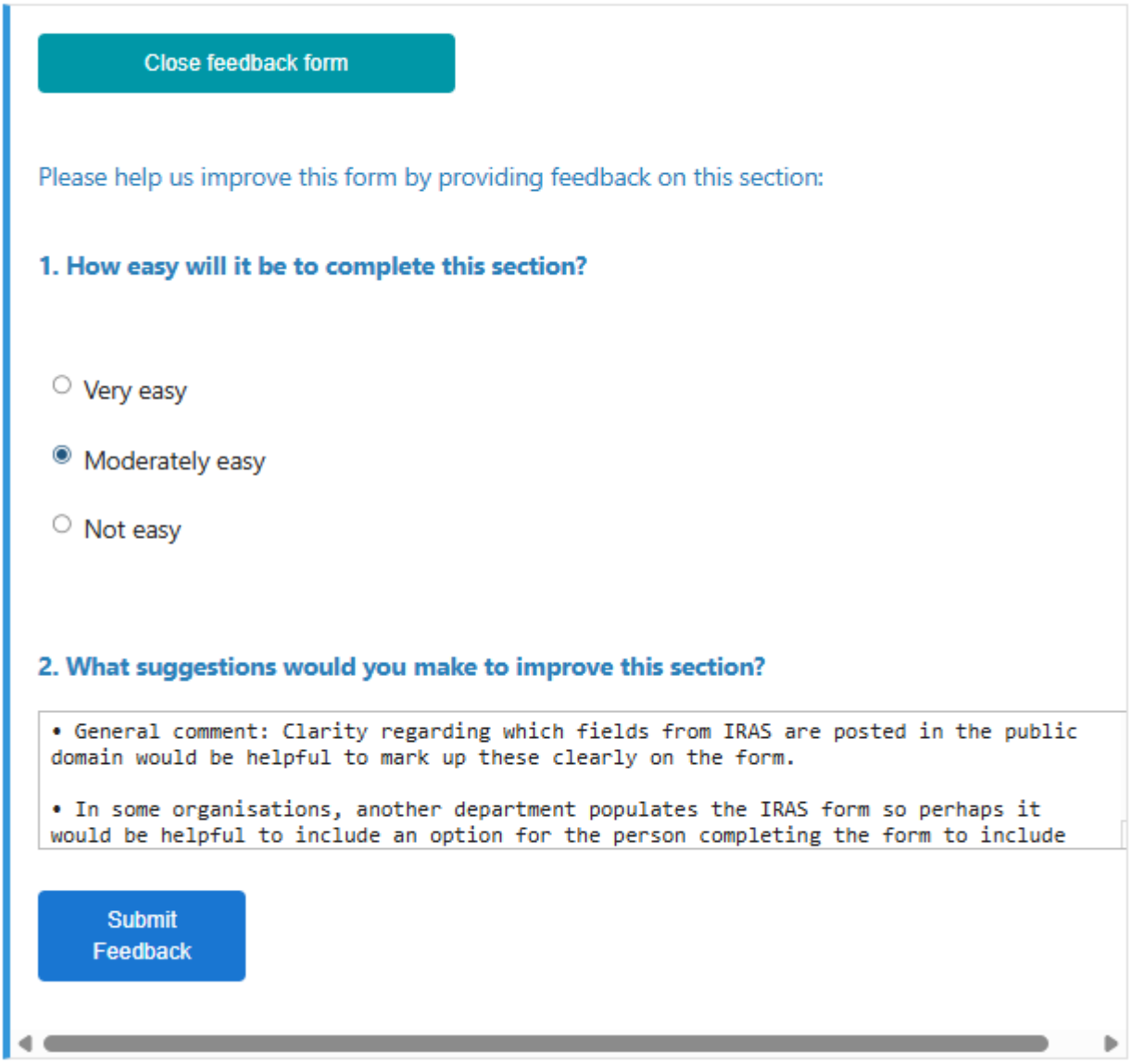
Close feedback form



Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

DATA SHARING

Close feedback form



E-mail office@phuse.global

Web www.phuse.global

PHUSE Limited
Company No: 05422297
VAT No: GB920 0529 64

PHUSE CTR
(wholly owned European subsidiary of PHUSE Limited)
Company No: 750562

PHUSE India Private Limited
Corporate Identity No: U82300PN2024FTC236151
GST No: 27AAPCP2555B1ZE
PAN No: AAPCP2555B

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

2. What suggestions would you make to improve this section?

additional member contact details allowing the form submission to also easily be viewed by the other interested groups regarding this activity, and which fields were selected to opt in for auto-registration so they can also prepare ahead for the next steps and maintain compliance.

Feedback Submitted

✅ Thank you! Your feedback has been submitted successfully.

2. What suggestions would you make to improve this section?

• Formatting: In instances where there is a prompt to select one option ("Please select one of the options below:"), square checkboxes are used. Typically, square boxes are used where multiple options can be selected. Therefore, suggestion to change square boxes to circular instead as circles are usually used when requiring only one option to be selected.

Feedback Submitted

✅ Thank you! Your feedback has been submitted successfully.

2. What suggestions would you make to improve this section?

option to be selected.

Note: This comment applies to all instances throughout the form where square boxes are used when only one option is required to be selected by the user.

Feedback Submitted

✅ Thank you! Your feedback has been submitted successfully.

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

PARTICIPANT FLOW

Close feedback form

Close feedback form

Please help us improve this form by providing feedback on this section:

1. How easy will it be to complete this section?

- ○ Very easy
- ○ Moderately easy
- ◉ Not easy

2. What suggestions would you make to improve this section?

• General comment regarding the "Mark All Complete" button in the top left corner of the main menu: Suggestion for the system to include additional verification and pointers for the required amendments (within each section and on the contents/main menu page) as this button may be selected without the record being completed correctly.

Feedback Submitted

✅ Thank you! Your feedback has been submitted successfully.

2. What suggestions would you make to improve this section?

• This section is complex and must be completed before being able to continue to the remaining sections. The system includes validation checks but could be improved for user-friendliness.

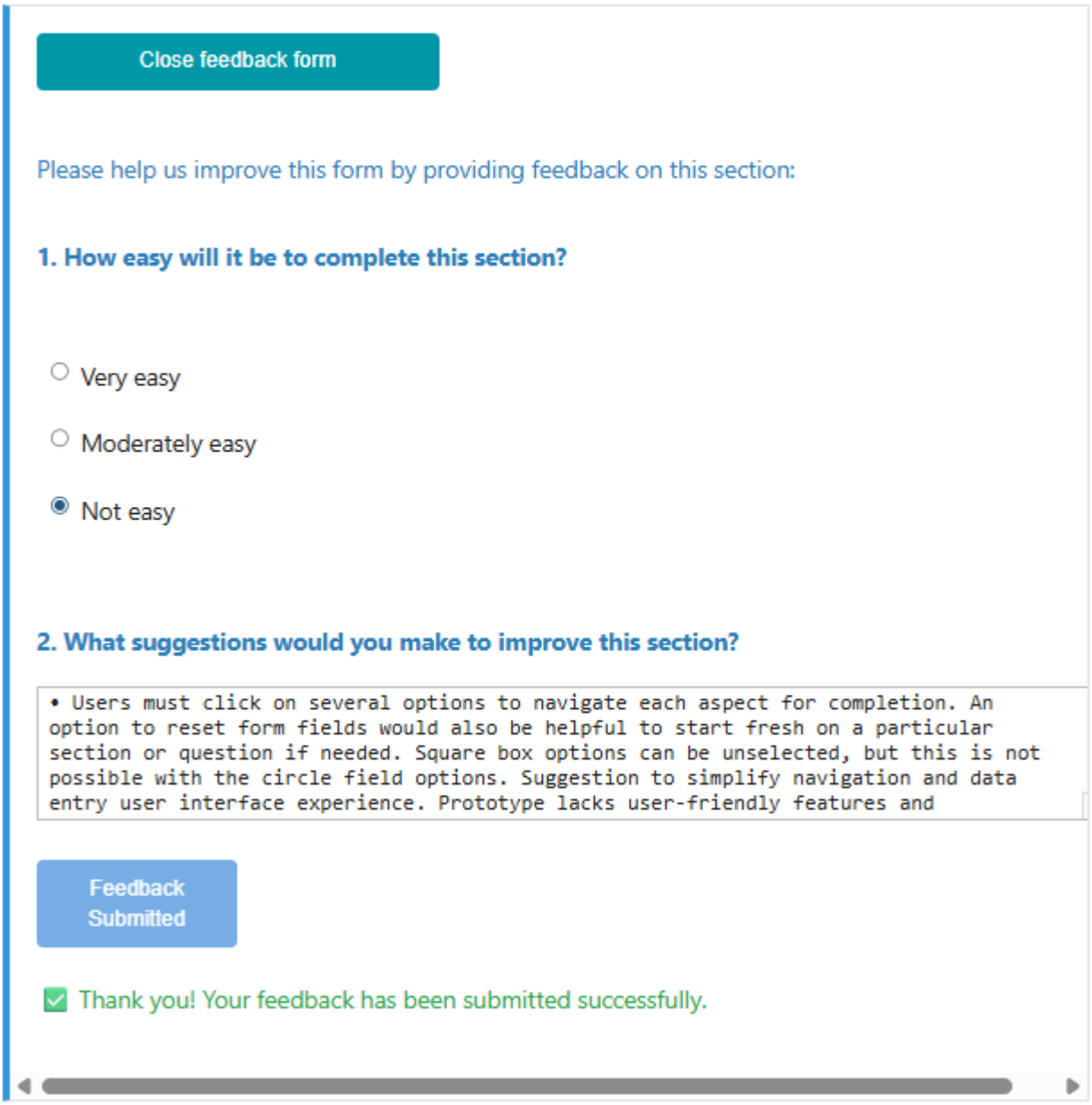
Feedback Submitted

✅ Thank you! Your feedback has been submitted successfully.

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

BASELINE PARTICIPANT CHARACTERISTICS – POPULATION 1

Close feedback form



Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

2. What suggestions would you make to improve this section?

documentation.

• For sex, there are options: male, female, not recorded as male or female. In some cases, for example there could be one female in the arm, when you provide more baseline characteristic information, you can get a profile of this patient. There

Feedback Submitted

✅ Thank you! Your feedback has been submitted successfully.

2. What suggestions would you make to improve this section?

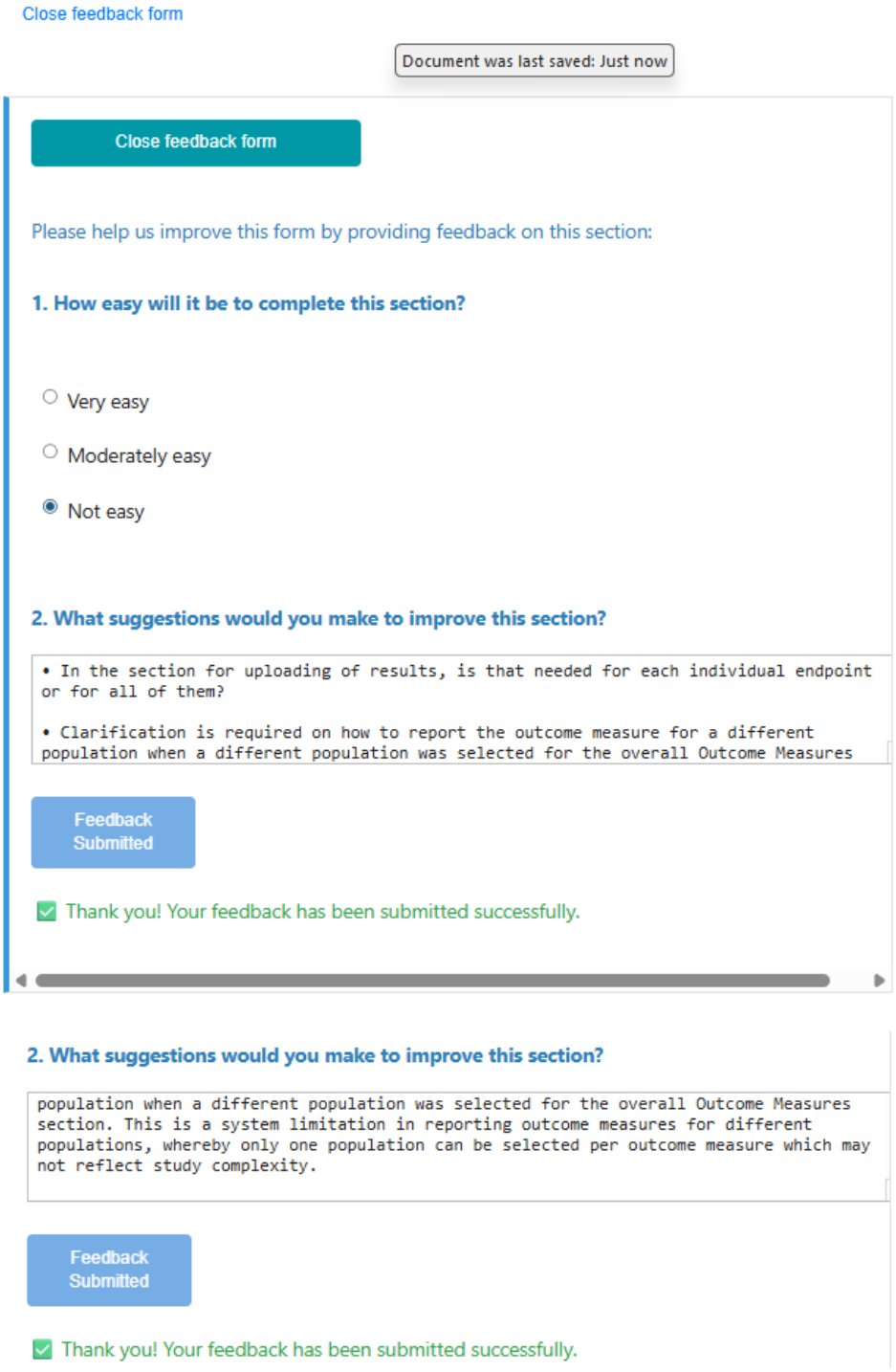
• For sex, there are options: male, female, not recorded as male or female. In some cases, for example there could be one female in the arm, when you provide more baseline characteristic information, you can get a profile of this patient. There should be an option either to show the baseline per overall study - in order not to build the profile of a particular patient where the arm is N=1

Feedback Submitted

✅ Thank you! Your feedback has been submitted successfully.

Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

OUTCOME MEASURES – POPULATION 1



2. What suggestions would you make to improve this section?

population when a different population was selected for the overall Outcome Measures section. This is a system limitation in reporting outcome measures for different populations, whereby only one population can be selected per outcome measure which may not reflect study complexity.

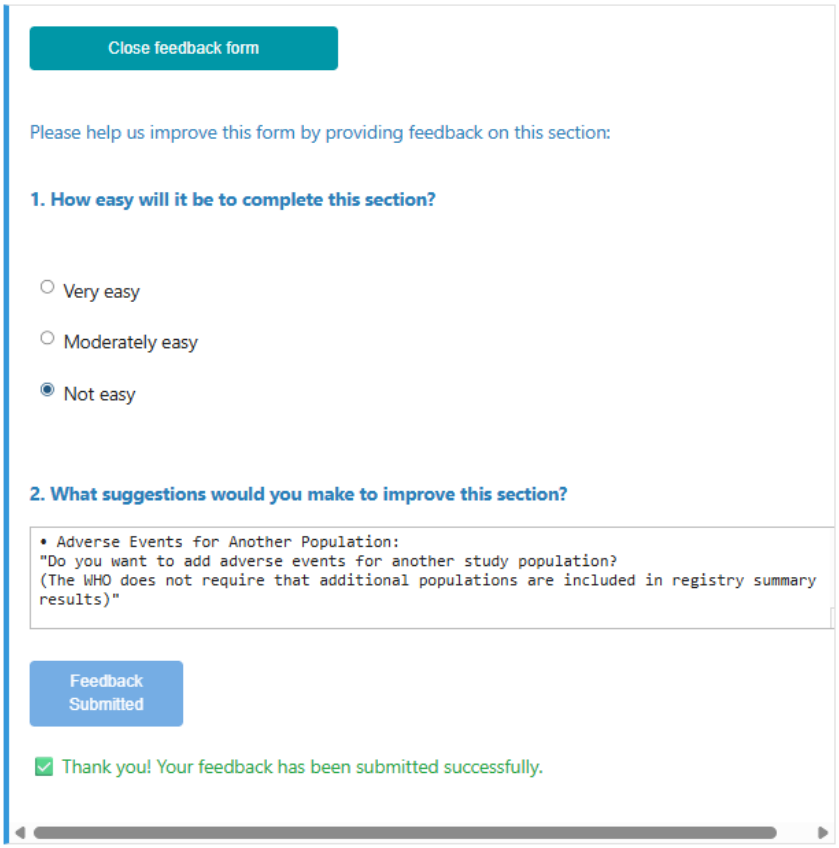
Feedback Submitted

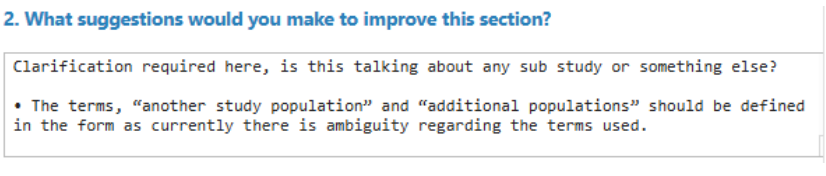
Thank you! Your feedback has been submitted successfully.

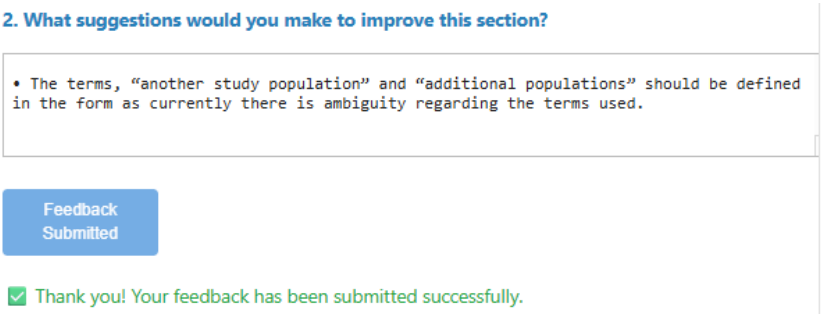
Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

ADVERSE EVENTS – POPULATION 1

Close feedback form



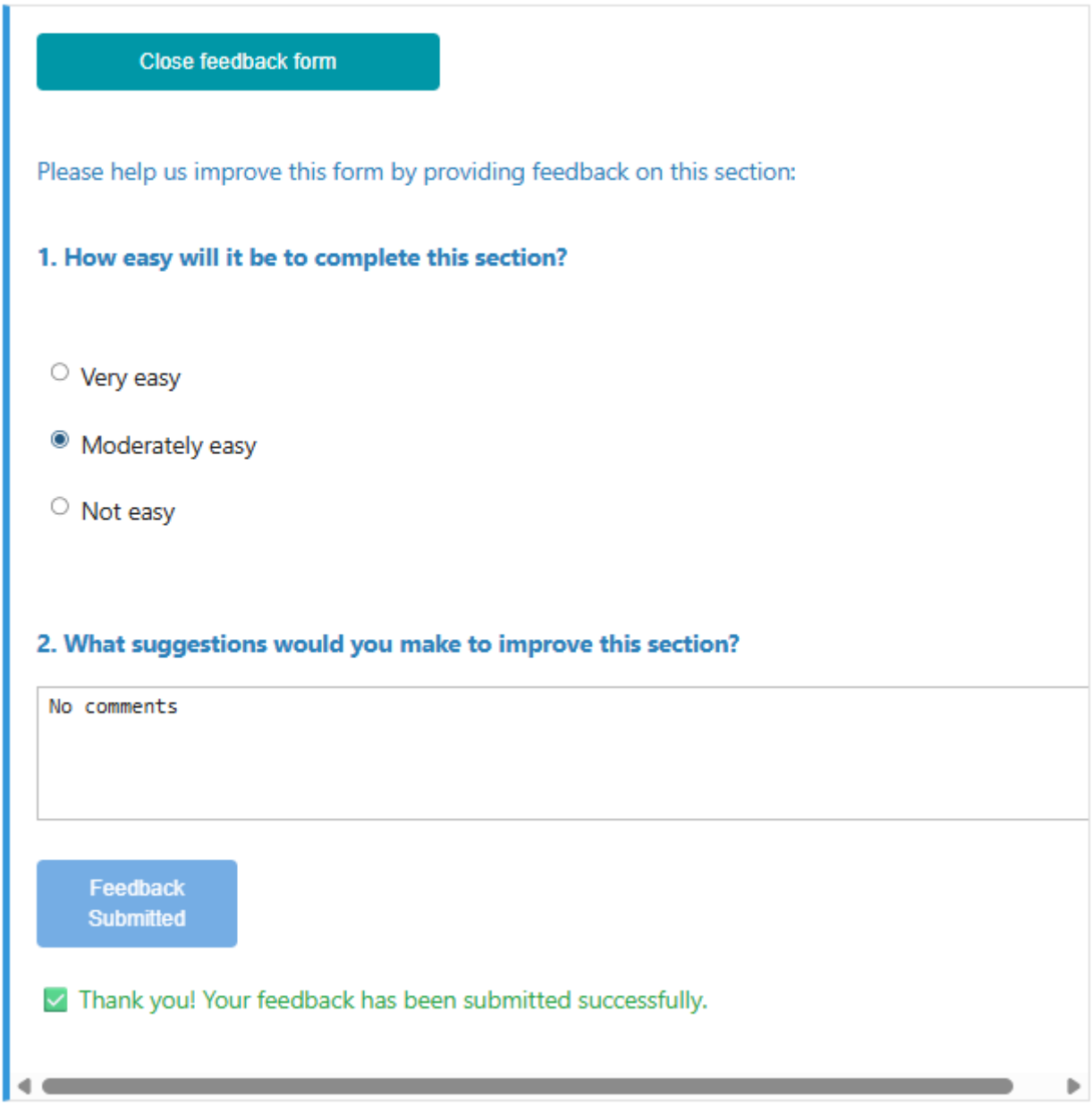




Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

STUDY CONCLUSION (Optional)

Close feedback form



Kent Innovation Centre
Millennium Way
Broadstairs
Kent
CT10 2QQ

SHARE REUSABLE DATA

Close feedback form

Close feedback form

Please help us improve this form by providing feedback on this section:

1. How easy will it be to complete this section?

- ○ Very easy
- ○ Moderately easy
- ◉ Not easy

2. What suggestions would you make to improve this section?

• PDF vs. CSV file uploading should be noted in each individual section where this is applicable. Also, suggestion to state clearly earlier on in the form specifying which sections a CSV would be acceptable. Currently, CSV uploads are only mentioned towards the end of the form within this 'Share Reusable Data' section. Recommendation to be more specific earlier on so users know before they reach the final section of the

Feedback Submitted

✅ Thank you! Your feedback has been submitted successfully.

2. What suggestions would you make to improve this section?

applicable. Also, suggestion to state clearly earlier on in the form specifying which sections a CSV would be acceptable. Currently, CSV uploads are only mentioned towards the end of the form within this 'Share Reusable Data' section. Recommendation to be more specific earlier on so users know before they reach the final section of the form.

Feedback Submitted

✅ Thank you! Your feedback has been submitted successfully.